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Federal Register

Friday
November 20, 1998

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FOR: Any person who uses the Federal Register and Code of Federal Regulations.
WHO: Sponosred by the Office of the Federal Register.
WHAT: Free public breifings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
2. The relationship between the Federal Register and Code of Federal Regulations.
3. The important elements of typical Federal Register documents.
4. An introduction to the finding aids of the FR/CFR system.

WHY: To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

WHEN: Tuesday, Nov. 24, 1998 at 9:00 am.
WHERE: Office of the Federal Register
Conference Room
800 North Capitol Street, NW.
Washington, DC
(3 blocks north of Union Station Metro)
RESERVATIONS: 202–523–4538

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket No. 98–082–3]

Mexican Fruit Fly Regulations; Addition of Regulated Area

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Mexican fruit fly regulations by expanding the regulated area in San Diego County, CA. This action is necessary on an emergency basis to prevent the spread of the Mexican fruit fly to noninfested areas of the United States. This action restricts the interstate movement of regulated articles from the newly regulated area in San Diego County, CA.

DATES: Interim rule effective November 16, 1998. Consideration will be given only to comments received on or before January 19, 1999.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 98–082–3, Regulatory Analysis and Development, PPD, APHIS, suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 98–082–3. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Stefan, Operations Officer, Domestic and Emergency Programs, PPQ, APHIS, 4700 River Road Unit 134, Riverdale, MD 20737–1236, (301) 734–8247; or e-mail: michael.b.stefan@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Mexican fruit fly, *Anastrepha ludens* (Loew), is a destructive pest of citrus and many other types of fruit. The short life cycle of the Mexican fruit fly allows rapid development of serious outbreaks that can cause severe economic losses in commercial citrus-producing areas.

The Mexican fruit fly regulations (contained in 7 CFR 301.64 through 301.64–10 and referred to below as the regulations) were established to prevent the spread of the Mexican fruit fly to noninfested areas of the United States. The regulations impose restrictions on the interstate movement of regulated articles from the regulated areas.

Section 301.64–3 provides that the Deputy Administrator for Plant Protection and Quarantine (PPQ), Animal and Plant Health Inspection Service (APHIS), shall list as a regulated area each quarantined State, or each portion of a quarantined State, in which the Mexican fruit fly has been found by an inspector, in which the Deputy Administrator has reason to believe the Mexican fruit fly is present, or that the Deputy Administrator considers necessary to regulate because of its proximity to the Mexican fruit fly or its inseparability for quarantine enforcement purposes from localities in which the Mexican fruit fly occurs.

Less than an entire quarantined State will be designated as a regulated area only if the Deputy Administrator determines that the State has adopted and is enforcing a quarantine or regulation that imposes restrictions on the intrastate movement of the regulated articles that are substantially the same as those that are imposed with respect to the interstate movement of the articles and the designation of less than the entire State as a regulated area will otherwise be adequate to prevent the artificial interstate spread of the Mexican fruit fly.

In an interim rule effective August 10, 1998, and published in the **Federal Register** on August 14, 1998 (63 FR 43603–43604, Docket No. 98–082–1), we designated a portion of the El Cajon area in San Diego County, CA, as a regulated area. In another interim rule effective October 16, 1998, and published in the **Federal Register** on October 22, 1998 (63 FR 56537–56539, Docket No. 98–082–2), we designated a portion of the San Diego area in San Diego County, CA, as a regulated area.

Recent trapping surveys by inspectors of California State and county agencies and by inspectors of PPQ reveal that an additional portion of San Diego County, CA, is infested with the Mexican fruit fly. Specifically, since October 16, 1998, inspectors have detected Mexican fruit flies near the boundaries of the previously regulated San Diego area of San Diego County, CA.

Accordingly, to prevent the spread of the Mexican fruit fly to noninfested areas of the United States, we are amending the regulations in § 301.64–3(c) by expanding the regulated area in the San Diego area of San Diego County, CA. The regulated area is described in the rule portion of this document.

There does not appear to be any reason to designate any other portions of the quarantined State of California as a regulated area. Officials of State agencies of California are conducting an intensive Mexican fruit fly eradication program in the regulated areas in California. Also, California has adopted and is enforcing regulations imposing restrictions on the intrastate movement of certain articles from the regulated areas that are substantially the same as those imposed with respect to the interstate movement of regulated articles.

The Mexican fruit fly is not known to occur anywhere else in the continental United States except in portions of Texas.

Emergency Action

The Administrator of the Animal and Plant Health Inspection Service has determined that an emergency exists that warrants publication of this interim rule without prior opportunity for public comment. Immediate action is necessary to prevent the Mexican fruit fly from spreading to noninfested areas of the United States.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make this action effective upon signature. We will consider comments that are received with 60 days of publication of this rule in the **Federal**

Register. After the comment period closes, we will publish another document in the **Federal Register**. The document will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required by Executive Order 12866.

This rule restricts the interstate movement of regulated articles from an additional area in San Diego County, CA. Within the regulated area there are approximately 109 small entities that may be affected by this rule. These include 86 fruit sellers, 6 nurseries, 16 wholesale distributors, and 1 grower. These 109 entities comprise less than 1 percent of the total number of similar entities operating in the State of California. Additionally, these small entities sell regulated articles primarily for local intrastate, not interstate, movement, so the effect, if any, of this regulation on these entities appears to be minimal.

The effect on those few entities that do move regulated articles interstate will be minimized by the availability of various treatments, that, in most cases, will allow these small entities to move regulated articles interstate with very little additional costs.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

Executive Order 12988

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rule; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this rule. The assessment provides a basis for the conclusion that the methods employed to eradicate the Mexican fruit fly will not present a risk of introducing or disseminating plant pests and will not have a significant impact on the quality of the human environment. Based on the finding of no significant impact, the Administrator of the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

The environmental assessment and finding of no significant impact were prepared in accordance with: (1) The National Environmental Policy Act of 1969, as amended (NEPA) (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Copies of the environmental assessment and finding of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect copies are requested to call ahead on (202) 690–2817 to facilitate entry into the reading room. In addition, copies may be obtained by writing to the individual listed under **FOR FURTHER INFORMATION CONTACT**.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Incorporation by reference, Plant diseases and pests, Quarantine, Reporting and recordkeeping requirements, Transportation.

Accordingly, we are amending 7 CFR part 301 as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for part 301 continues to read as follows:

Authority: 7 U.S.C. 147a, 150bb, 150dd, 150ee, 150ff, 161, 162, and 164–167; 7 CFR 2.22, 2.80, and 371.2(c).

2. In § 301.64–3, paragraph (c), the entry for California is revised to read as follows:

§ 301.64–3 Regulated areas.

* * * * *

(c) * * *

CALIFORNIA

San Diego County.

El Cajon area—That portion of San Diego County bounded by a line drawn as follows: Beginning at the intersection of State Highway 67 and Mapleview Street; then east along Mapleview Street to Lake Jennings Park Road; then southeast along Lake Jennings Park Road to El Monte Road; then east along an imaginary line to the intersection of Blossom Valley Road and Flinn Springs Road; then southeast along Flinn Springs Road to Olde Highway 80; then east along Olde Highway 80 to Dunbar Lane; then south along Dunbar Lane to Alpine Boulevard; then southeast along Alpine Boulevard to Arnold Way; then south along Arnold Way to Harblson Canyon Road; then southwest along Harblson Canyon Road to Dehesa Road; then southwest along Dehesa Road to Sloane Canyon Road; then west along an imaginary line to the intersection of Willow Glenn Drive and Hillsdale Road; then northwest and west along Hillsdale Road to State Highway 54; then north along State Highway 54 to Chase Avenue; then west along Chase Avenue to Rolling Hills Drive; then west along Rolling Hills Drive to Fuerte Drive; then southwest, west, and northwest along Fuerte Drive to Severin Drive; then north along Severin Drive to Interstate Highway 8; then northeast along Interstate Highway 8 to Russell Road; then west along Russell Road to Cuyamaca Street; then north along Cuyamaca Street to Mission Gorge Road; then east along Mission Gorge Road to Woodside Avenue; then northeast along Woodside Avenue to State Highway 67; then northeast along State Highway 67 to the point of beginning.

San Diego area—That portion of San Diego County bounded by a line drawn as follows: Beginning at the intersection of Mission Gorge Road and Jackson Drive; then southeast along Jackson Drive to Grossmont Boulevard; then east along Grossmont Boulevard to State Highway 125; then south along State Highway 125 to Spring Street; then southeast along Spring Street to Broadway; then southwest along Broadway to Sweetwater Road; then south along Sweetwater Road to South Bay Parkway; then southwest along South Bay Parkway to State Highway 54; then southwest along State Highway 54 to Interstate Highway 5; then southwest along an imaginary line to the intersection of the northern boundary of Silver Strand State Beach and the Pacific Ocean coastline, on the west side of the Coronado Peninsula; then northwest and northeast along the Pacific Ocean coastline to the Wright Avenue Pier; then northwest along an imaginary line to the intersection of Harbor Drive and Nimitz Boulevard; then northwest along Nimitz Boulevard to Rosecrans Street; then northeast along Rosecrans Street to Interstate Highway 5; then north along Interstate Highway 5 to Interstate Highway 8; then northeast along Interstate Highway 8 to Interstate Highway 15; then north along Interstate Highway 15 to Friars Road; then northeast along Friars Road

to Mission Gorge Road; then northeast along Mission Gorge Road to the point of beginning.

* * * * *

Done in Washington, DC, this 16th day of November 1998.

Joan M. Arnoldi,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 98–31061 Filed 11–19–98; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98–AGL–54]

Modification of Class E Airspace; Owatonna, MN

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action modifies Class E airspace at Owatonna, MN. A VHF Omnidirectional Range/Distance Measuring Equipment (VOR/DME) Standard Instrument Approach Procedure (SIAP) to Runway (Rwy) 30, Amendment 4, has been developed for Owatonna Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This action increases the radius of, and adds a southeast extension to, the existing controlled airspace for this airport.

EFFECTIVE DATE: 0901 UTC, January 28, 1999.

FOR FURTHER INFORMATION CONTACT: Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL–520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294–7568.

SUPPLEMENTARY INFORMATION:

History

On Wednesday, September 9, 1998, the FAA proposed to amend 14 CFR part 71 to modify Class E airspace at Owatonna, MN (63 FR 48143). The proposal was to add controlled airspace extending upward from 700 to 1200 feet AGL to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies Class E airspace at Owatonna, MN, to accommodate aircraft executing the proposed VOR/DME Rwy 30 SIAP, Amendment 4, at Owatonna Municipal Airport by increasing the radius of, and adding a southeast extension to, the existing controlled airspace for the airport. The area will be depicted on appropriate aeronautical charts.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AGL MN E5 Owatonna, MN [Revised]

Owatonna Municipal Airport, MN
(lat. 44° 07′ 18″N., long. 93° 15′ 27″W.)
Halfway VOR/DME
(lat. 44° 12′ 16″N., long. 93° 22′ 14″W.)

That airspace extending upward from 700 feet above the surface within an 6.7-mile radius of the Owatonna Municipal Airport, and within 1.7 miles each side of the Halfway VOR/DME 135° radial extending from the 6.7-mile radius of the airport to 14.0 miles southeast of the halfway VOR/DME, excluding that airspace within the Waseca, MN, Class E airspace area.

* * * * *

Issued in Des Plaines, Illinois on November 6, 1998.

Maureen Woods,

Manager, Air Traffic Division.

[FR Doc. 98–31026 Filed 11–19–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 295

[Docket No. 980717184–8277–02]

RIN 0693–AB48

Advanced Technology Program

AGENCY: National Institute of Standards and Technology, Technology Administration, Commerce.

ACTION: Final rule.

SUMMARY: The National Institute of Standards and Technology is today issuing a final rule which amends the implementing regulations for the Advanced Technology Program (ATP). Changes include modification of the ATP evaluation criteria and weights for project selection and clarification of other sections of the rule.

EFFECTIVE DATE: This rule is effective November 20, 1998.

FOR FURTHER INFORMATION CONTACT: To receive additional program information, contact Barbara Lambis at 301–975–4447.

SUPPLEMENTARY INFORMATION: The National Institute of Standards and Technology is today issuing a final rule which amends regulations found at Part 295 of Title 15 of the Code of Federal

Regulations, which implements the Advanced Technology Program (ATP). These changes strengthen the fundamental mission of the ATP; for government to work in partnership with industry to foster the development and broad dissemination of challenging, high-risk technologies that offer the potential for significant, broad-based economic benefits for the nation. Such a unique government-industry research partnership fosters dramatic gains in existing industries, accelerates the development of emerging or enabling technologies leading to revolutionary new products, industrial processes and services for the world's markets, and helps spawn new industries of the 21st century. Furthermore, the changes also ensure that the fundamental strengths of the ATP remain unchanged, especially the requirement that the ATP continue to be a wholly merit-driven program based on peer review. Changes to Part 295 include revisions on the following topics (please see the analysis of comments below for additional details):

- Section 295.2, Definitions, is modified to add a definition of ''company'' for clarity; revises the definition of ''industry-led joint research and development venture'' for clarity; and removes the definition of ''joint research and development venture'' or ''joint venture'' which is already included in the ATP statute.
- Section 295.4, The selection process, is modified to eliminate funding to assist proposers in overcoming any organizational deficiencies because the adequacy of the organizational structure is included in one of the ATP selection criteria.
- Section 295.6, Criteria for selection, is modified to place equal emphasis on the technical and economic merits of a proposal in accordance with the purpose of the Program.
- Sections 295.10 and 295.11 are removed because they are operational procedures unnecessary for inclusion in a regulation.
- Redesignated section 295.11, NIST technical and educational services for ATP recipients, is modified to add educational services to be provided to ATP recipients.
- Section 295.21, Qualifications of proposers, is modified to state that for joint ventures, costs will only be allowed after the execution of the joint venture agreement and approval by NIST.
- Also, a number of administrative and clerical changes are implemented to sections 295.5, 295.7, 295.8, and 295.24 for consistency and clarity.

Summary of Comments

On September 25, 1998, NIST published a notice of proposed rulemaking in the **Federal Register** (63 FR 51307). In response to this notice three comments were received; two from associations representing universities and one from a state entity. An analysis of the comments follows.

Section 295.2 Definitions—(2 Comments)

One commenter stated that the definition of ''company'' should include ''limited liability company (LLC). Another commenter raised concern that the current and proposed definition of a joint venture imposes restrictions on the participation of universities and urged that it be conceptualized as broadly as possible so that universities can more fully participate in partnership with private industry.

NIST Response: ATP accepts the suggestion to include limited liability partnership in the definition and the change is reflected herein. No change is made with respect to the second comment since the definition of a joint venture already offers universities the opportunity to participate in partnership with the private industry and the ATP statute requires joint ventures to be industry-led.

Section 295.5 Use of Pre-proposals in the Selection Process—(1 Comment)

One commenter stated that it was uncertain from the proposed change whether or not proposers are ''accepted'' or ''rejected'' at the pre-proposal stage, or whether they are just given feedback as to how they can improve their full proposal.

NIST Response: To clarify any uncertainty, the section is modified to indicate that written feedback is provided to the proposers to determine whether the proposed projects appear sufficiently promising to warrant further development into full proposals and that proposals are neither ''accepted'' or ''rejected'' at the pre-proposal stage.

Section 295.6 Criteria for Selection—(1 Comment)

One commenter stated that the criteria may be too broad and suggested that ATP add some level of breakdown of each major category to better guide proposers in the proposal development process.

NIST Response: Some level of breakdown of each of the two major categories is included in this section. The ATP Proposal Preparation Kit will help guide proposers further in the proposal development process by providing detailed information about the types of documentation that will fulfill the evaluation criteria.

Section 295.7 Notice of Availability of Funds—(1 Comment)

One commenter suggested that information on pre-proposals be added to be consistent with section 295.5.

NIST Response: Since NIST may use mandatory or optional pre-proposals, the appropriate Commerce Business Daily notice and ATP Proposal Preparation Kit will provide the appropriate information.

Section 295.8 Intellectual Property Rights: Publication of Research Results—(3 Comments)

Two commenters raised opposition to the restriction that title to inventions arising from ATP funded projects must vest in a company or companies incorporated in the United States and requested that the proposed rulemaking be deferred until this is resolved or the restriction be lifted to include universities. Another commenter suggested that this section be modified to require companies to list their ''background intellectual property rights'' they bring to the program at the beginning of the project, so there is no confusion as to what is actually developed in the course of the technology development.

NIST Response: The proposed rule made no change to the ATP patent policy. Since NIST did not seek public comment on the ATP patent policy, no changes are made here. No change is made with respect to the second comment because requiring the companies to list their ''background intellectual property rights'' they bring to the program at the beginning of the project would cause a significant burden on the companies and is unnecessary.

Additional Information

Effective Date of Final Rule

Pursuant to authority at 5 U.S.C. 553(a)(2), this final rule relating to grants, benefits, and contracts is exempt from the delayed effective date requirement of 5 U.S.C. 553(d), and is therefore being made effective immediately without a 30 day delay in effective date.

Executive Order 12866

This rule has been determined to be significant under section 3(f) of Executive Order 12866.

Executive Order 12612

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism

assessment under Executive Order 12612.

Regulatory Flexibility Act

The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy, Small Business Administration, that this rule, if promulgated, will not have a significant economic effect on a substantial number of small entities. (5 U.S.C. 605(b)). This is because there are only a small number of awardees and thus only a small number of awards will be given to small businesses. Specifically, based on past experience and currently foreseen budgets, the ATP would expect to receive only a few hundred proposals annually from small businesses, and from these, to make under 100 awards. Seeking ATP funding is entirely voluntary. No comments were received regarding this certification. As such, a final regulatory flexibility analysis is not required and none has been prepared.

Paperwork Reduction Act

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection-of-information, subject to the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number.

This rule contains collection of information requirements subject to review and approval by the OMB under the PRA. The collection of information requirement applies to persons seeking financial assistance under the ATP as well as reporting requirements if financial assistance is granted. The collection of information requirements have been approved under OMB Control Number 0693–0009 and 0651–0032. The public reporting burden per respondent for the collection of information contained in this rule is estimated to range between 20 and 30 hours per submission and 3 hours annually for recipients of financial assistance to provide monitoring reports. This estimate includes the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Comments on the burden estimates, or any other aspect of the information requirements, should be addressed to Barbara Lambis, National Institutes of Standards and Technology; Advanced Technology Program; 100 Bureau Drive, Stop 4700; Administration Bldg. 101, Room A333; Gaithersburg, MD 20899–4700.

National Environmental Policy Act

This rule will not significantly affect the quality of the human environment. Therefore, an environmental assessment or Environmental Impact Statement is not required to be prepared under the National Environmental Policy Act of 1969.

Executive Order 12372

Executive Order 12372 ''Intergovernmental Review of Federal Programs'' does not apply to this Program.

List of Subjects in 15 CFR Part 295

Inventions and patents, Laboratories, Research and development, Science and technology.

Dated: November 16, 1998.

Robert E. Hebner,

Acting Deputy Director, National Institute of Standards and Technology.

For reasons set forth in the preamble, Title 15, Part 295 of the Code of Federal Regulations is amended as follows:

PART 295—ADVANCED TECHNOLOGY PROGRAM

1. The authority citation for Part 295 continues to read as follows:

Authority: 15 U.S.C. 278n.

2. Section 295.2 is amended by removing paragraph (j), redesignating paragraphs (b) through (i) as paragraphs(c) through (j), revising newly redesignated paragraph (i), and adding new paragraph (b) to read as follows:

§ 295.2 Definitions.

* * * * *

(b) The term ''company'' means a for-profit organization, including sole proprietors, partnerships, limited liability companies (LLCs), or corporations.

* * * * *

(i) The term ''industry-led joint research and development venture'' or ''joint venture'' means a business arrangement that consists of two or more separately-owned, for-profit companies that perform research and development in the project; control the joint venture's membership, research directions, and funding priorities; and share total project costs with the Federal government. The joint venture may include additional companies, independent research organizations, universities, and/or governmental laboratories (other than NIST) which may or may not contribute funds (other than Federal funds) to the project and perform research and development. A for-profit company or an independent research organization may serve as an Administrator and perform administrative tasks on behalf of a joint venture, such as handling receipts and disbursements of funds and making antitrust filings. The following activities are not permissible for ATP funded joint ventures:

(1) Exchanging information among competitors relating to costs, sales, profitability, prices, marketing, or distribution of any product, process, or service that is not reasonably required to conduct the research and development that is the purpose of such venture;

(2) Entering into any agreement or engaging in any other conduct restricting, requiring, or otherwise involving the production or marketing by any person who is a party to such joint venture of any product, process, or service, other than the production or marketing of proprietary information developed through such venture, such as patents and trade secrets; and

(3) Entering into any agreement or engaging in any other conduct:

(i) To restrict or require the sale, licensing, or sharing of inventions or developments not developed through such venture, or

(ii) To restrict or require participation by such party in other research and development activities, that is not reasonably required to prevent misappropriation of proprietary information contributed by any person who is a party to such venture or of the results of such venture.

* * * * *

4. Section 295.4 is revised to read as follows:

§ 295.4 The selection process.

(a) The selection process for awards is a multi-step process based on the criteria listed in § 295.6. Source evaluation boards (SEB) are established to ensure that all proposals receive careful consideration. In the first step, called ''preliminary screening,'' proposals may be eliminated by the SEB that do not meet the requirements of this Part of the annual **Federal Register** Program announcement. Typical but not exclusive of the reasons for eliminating a proposal at this stage are that the proposal: is deemed to have serious deficiencies in either the technical or business plan; involves product development rather than high-risk R&D; is not industry-led; is significantly overpriced or underpriced given the scope of the work; does not meet the requirements set out in the notice of availability of funds issued pursuant to

§ 295.7; or does not meet the cost-sharing requirement. NIST will also examine proposals that have been submitted to a previous competition to determine whether substantive revisions have been made to the earlier proposal, and, if not, may reject the proposal.

(b) In the second step, referred to as the ''technical and business review,'' proposals are evaluated under the criteria found in § 295.6. Proposals judged by the SEB after considering the technical and business evaluations to have the highest merit based on the selection criteria receive further consideration and are referred to as ''semifinalists.''

(c) In the third step, referred to as ''selection of finalists,'' the SEB prepares a final ranking of semifinalist proposals by a majority vote, based on the evaluation criteria in § 295.6. During this step, the semifinalist proposers will be invited to an oral review of their proposals with NIST, and in some cases site visits may be required. Subject to the provisions of § 295.6, a list of ranked finalists is submitted to the Selecting Official.

(d) In the final step, referred to as ''selection of recipients,'' the Selecting Official selects funding recipients from among the finalists, based upon: the SEB rank order of the proposals on the basis of all selection criteria (§ 295.6); assuring an appropriate distribution of funds among technologies and their applications; the availability of funds; and adherence to the Program selection criteria. The Program reserves the right to deny awards in any case where information is uncovered which raises a reasonable doubt as to the responsibility of the proposer. The decision of the Selecting Official is final.

(e) NIST reserves the right to negotiate the cost and scope of the proposed work with the proposers that have been selected to receive awards. For example, NIST may request that the proposer delete from the scope of work a particular task that is deemed by NIST to be product development or otherwise inappropriate for ATP support.

5. Section 295.5 is revised to read as follows:

§ 295.5 Use of pre-proposals in the selection process.

To reduce proposal preparation costs incurred by proposers and to make the selection process more efficient, NIST may use mandatory or optional preliminary qualification processes based on pre-proposals. In such cases, announcements requesting pre-proposals will be published as indicated in § 295.7, and will seek abbreviated proposals (pre-proposals) that address both of the selection criteria, but in considerably less detail than full proposals. The Program will review the pre-proposals in accordance with the selection criteria and provide written feedback to the proposers to determine whether the proposed projects appear sufficiently promising to warrant further development into full proposals. Proposals are neither ''accepted'' or ''rejected'' at the pre-proposal stage. When the full proposals are received in response to the notice of availability of funds described in § 295.7, the review and selection process will occur as described in § 295.4.

6. Section 295.6 is revised to read as follows:

§ 295.6 Criteria for selection.

The evaluation criteria to be used in selecting any proposal for funding under this program, and their respective weights, are listed in this section. No proposal will be funded unless the Program determines that it has scientific and technological merit and that the proposed technology has strong potential for broad-based economic benefits to the nation. Additionally, no proposal will be funded that does not require Federal support, that is product development rather than high risk R&D, that does not display an appropriate level of commitment from the proposer, or does not have an adequate technical and commercialization plan.

(a) *Scientific and Technological Merit (50%).* The proposed technology must be highly innovative. The research must be challenging, with high technical risk. It must be aimed at overcoming an important problem(s) or exploiting a promising opportunity. The technical leverage of the technology must be adequately explained.

The research must have a strong potential for advancing the state of the art and contributing significantly to the U.S. scientific and technical knowledge base. The technical plan must be clear and concise, and must clearly identify the core innovation, the technical approach, major technical hurdles, the attendant risks, and clearly establish feasibility through adequately detailed plans linked to major technical barriers. The plan must address the questions of ''what, how, where, when, why, and by whom'' in substantial detail. The Program will assess the proposing team's relevant experience for pursuing the technical plan. The team carrying out the work must demonstrate a high level of scientific/technical expertise to conduct the R&D and have access to the necessary research facilities.

(b) *Potential for broad-based economic benefits (50%).* The proposed technology must have a strong potential to generate substantial benefits to the nation that extend significantly beyond the direct returns to the proposing organization(s). The proposal must explain why ATP support is needed and what difference ATP funding is expected to make in terms of what will be accomplished with the ATP funding versus without it. The pathways to economic benefit must be described, including the proposer's plan for getting the technology into commercial use, as well as additional routes that might be taken to achieve broader diffusion of the technology. The proposal should identify the expected returns that the proposer expects to gain, as well as returns that are expected to accrue to others, i.e., spillover effects. The Program will assess the proposer's relevant experience and level of commitment to the project and project's organizational structure and management plan, including the extent to which participation by small businesses is encouraged and is a key component in a joint venture proposal, and for large company single proposers, the extent to which subcontractor/subrecipient teaming arrangements are featured and are a key component of the proposal.

7. Section 295.7 is revised to read as follows:

§ 295.7 Notice of availability of funds.

The Program shall publish at least annually a **Federal Register** notice inviting interested parties to submit proposals, and may more frequently publish invitations for proposals in the Commerce Business Daily, based upon the annual notice. Proposals must be submitted in accordance with the guidelines in the ATP Proposal Preparation Kit as identified in the published notice. Proposals will only be considered for funding when submitted in response to an invitation published in the **Federal Register**, or a related announcement in the Commerce Business Daily.

8. Section 295.8(a)(1) and 295.8(a)(2) are revised to read as follows:

§ 295.8 Intellectual property rights; Publication of research results.

(a)(1) *Patent Rights.* Title to inventions arising from assistance provided by the Program must vest in a company or companies incorporated in the United States. Joint ventures shall provide to NIST a copy of their written agreement which defines the disposition of ownership rights among the members of the joint venture, and their contractors and subcontractors as appropriate, that complies with the first

sentence of this paragraph. The United States will reserve a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any such intellectual property, but shall not, in the exercise of such license, publicly disclose proprietary information related to the license. Title to any such intellectual property shall not be transferred or passed, except to a company incorporated in the United States, until the expiration of the first patent obtained in connection with such intellectual property. Nothing in this paragraph shall be construed to prohibit the licensing to any company of intellectual property rights arising from assistance provided under this section.

(2) *Patent Procedures.* Each award by the Program shall include provisions assuring the retention of a governmental use license in each disclosed invention, and the government's retention of march-in rights. In addition, each award by the Program will contain procedures regarding reporting of subject inventions by the funding Recipient to the Program, including the subject inventions of members of the joint venture (if applicable) in which the funding Recipient is a participant, contractors and subcontractors of the funding Recipient. The funding Recipient shall disclose such subject inventions to the Program within two months after the inventor discloses it in writing to the Recipient's designated representative responsible for patent matters. The disclosure shall consist of a detailed, written report which provides the Program with the following: the title of the present invention; the names of all inventors; the name and address of the assignee (if any); an acknowledgment that the United States has rights in the subject invention; the filing date of the present invention, or, in the alternative, a statement identifying that the Recipient determined that filing was not feasible; an abstract of the disclosure; a description or summary of the present invention; the background of the present invention or the prior art; a description of the preferred embodiments; and what matter is claimed. Upon issuance of the patent, the funding Recipient or Recipients must notify the Program accordingly, providing it with the Serial Number of the patent as issued, the date of issuance, a copy of the disclosure as issued, and if appropriate, the name, address, and telephone number(s) of an assignee.

* * * * *

§§ 295.10 and 295.11 [Removed]

§§ 295.12 and 295.13 [Redesignated as sections 295.10 and 295.11]

9. Sections 295.10 and 295.11 are removed and §§ 295.12 and 295.13 are redesignated as §§ 295.10 and 295.11.

10. The newly redesignated § 295.11 is amended by revising the heading and by adding a new paragraph (c) to read as follows:

§ 295.11 Technical and educational services for ATP recipients.

* * * * *

(c) From time to time, ATP may conduct public workshops and undertake other educational activities to foster the collaboration of funding Recipients with other funding resources for purposes of further development and commercialization of ATP-related technologies. In no event will ATP provide recommendations, endorsements, or approvals of any ATP funding Recipients to any outside party.

11. Section 295.21 is revised to read as follows:

§ 295.21 Qualifications of proposers.

Subject to the limitations set out in § 295.3, assistance under this subpart is available only to industry-led joint research and development ventures. These ventures may include universities, independent research organizations, and governmental entities. Proposals for funding under this Subpart may be submitted on behalf of a joint venture by a for-profit company or an independent research organization that is a member of the joint venture. Proposals should include letters of commitment or excerpts of such letters from all proposed members of the joint venture, verifying the availability of cost-sharing funds, and authorizing the party submitting the proposal to act on behalf of the venture with the Program on all matters pertaining to the proposal. No costs shall be incurred under an ATP project by the joint venture members until such time as a joint venture agreement has been executed by all of the joint venture members and approved by NIST. NIST will withhold approval until it determines that a sufficient number of members have signed the joint venture agreement. Costs will only be allowed after the execution of the joint venture agreement and approval by NIST.

12. Section 295.24 is revised to read as follows:

§ 295.24 Registration.

Joint ventures selected for funding under the Program must notify the Department of Justice and the Federal Trade Commission under the National Cooperative Research Act of 1984. No funds will be released prior to receipt by the Program of copies of such notification.

[FR Doc. 98–30956 Filed 11–17–98; 2:55 pm]
BILLING CODE 3510–13–M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[AZ–001–BU; FRL–6183–7]

Clean Air Act Reclassification; Arizona-Phoenix Nonattainment Area; Ozone; Extension of Plan Submittal Deadline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: On November 6, 1997, EPA published a rule announcing our finding that the Phoenix, Arizona, metropolitan area had failed to attain the 1-hour national ambient air quality standard for ozone as required by the Federal Clean Air Act (CAA or the Act). This finding resulted in the area being reclassified by operation of law from a ''moderate'' to a ''serious'' ozone nonattainment area. In the rule, we also set a deadline of December 8, 1998 for Arizona to submit the revisions to its implementation plan that are needed to meet the Act's requirements for serious ozone nonattainment areas. In this action, we are extending the submittal deadline to March 22, 1999.

DATES: This rule is effective on January 4, 1999 without further notice, unless EPA receives adverse comments by December 7, 1998. If EPA receives such comment, it will publish a timely withdrawal **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Please address comment to Frances Wicher, Office of Air Planning (AIR–2), U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California 94105. We have also placed a copy of this document in the air programs section of our website at www.epa.gov/region09/air.

FOR FURTHER INFORMATION CONTACT: Frances Wicher at (415) 744–1248 or wicher.frances@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

What Action Is EPA Taking in This Rule?

EPA is extending by three and one-half months, until March 22, 1999, the

date by which the State of Arizona must submit the revisions to the Phoenix metropolitan area's state implementation plan (SIP) that are needed to meet the Clean Air Act's requirements for serious ozone nonattainment areas. These revisions include a demonstration that the area will meet the 1-hour ozone standard as expeditiously as practicable but no later than November 15, 1999; a demonstration that the plan provides for at least a 9 percent reduction in ozone precusors; a current, comprehensive, and accurate emissions inventory; an enhanced vehicle inspection and maintenance program; and contingency measures.[1]

The previous submittal deadline for the serious area plan was December 8, 1998. We set this date at the same time we found the Phoenix moderate ozone nonattainment area had failed to attain the ozone standard by its required deadline of November 15, 1996. See 62 FR 60001 (November 6, 1997).

What Is EPA's Authority To Set Submittal Dates?

When an area is reclassified, we have the authority under section 182(i) of the Act to adjust the Act's submittal deadlines for any new SIP revisions that are required as a result of the reclassification. If a State fails to submit a complete plan by the required deadline, the area is potentially subject to sanctions and a federally-imposed implementation plan under sections 179(a) and 110(c) of the Act.

Why Did EPA Originally Set the Submittal Deadline at December 8, 1998?

The Phoenix reclassification was proposed on September 2, 1997. See 62 FR 46229. At that time, we also proposed that the serious area plan be due twelve months from the effective date of the final reclassification. We selected the 12-month schedule instead of the more usual 18-month schedule for submittal of a revised plan in order to ensure that the revised air quality plan would be submitted before the beginning of the ''ozone season'' in 1999. The ozone season generally occurs during the summer months from mid-May to October when high temperatures and extended daylight hours create the conditions most conducive to ozone formation. Setting the submittal deadline before the beginning of the 1999 ozone season helps ensure that additional controls would be in place to reduce ozone concentrations during this season. The 1999 ozone season is the one that procedes the November 15, 1999 attainment deadline for serious ozone nonattainment areas.

For Phoenix, we received comments opposing the 12-month deadline as too short to develop the needed plan; however, none of the commenters proposed an alternative time frame. We, therefore, set a submittal deadline of 12 months from the effective date of the final reclassification. For Phoenix, this resulted in a December 8, 1998 submittal deadline.[2]

What Impact Will Extending the Deadline Have on the Area's Ability to Attain the 1-Hour Ozone Standard?

In Phoenix, high levels of ozone are most likely to occur during the ozone season from mid-May until late September. To reduce ozone concentrations in the upcoming 1999 ozone season, the State will need to implement additional controls prior to the beginning of this ozone season. The March 22 submittal deadline for the serious area plan is still well before the beginning of the Phoenix ozone season; therefore, extending that deadline should not affect the State's ability to implement needed controls by the beginning of the 1999 ozone season. However, the March 22 deadline still provides us with an approximately 60-day period prior to the start of the ozone season for determining that the State has submitted a complete plan. For this reason, we do not believe that the extension of the submittal deadline will adversely impact air quality in the Phoenix area.

II. What If I Want To Comment on This Action?

We are publishing this rule as a ''direct'' final action without first proposing the rule and providing an opportunity for public comment. We are finalizing this rule directly because we believe this is noncontroversial and do not expect to receive unfavorable comments on it. However, in the ''proposed rules'' section of this **Federal Register** publication, we are also publishing a separate document to serve as the proposal should adverse comments be received. This final rule will be effective January 4, 1999 without further notice from us unless we receive unfavorable comments by December 7, 1998.

If we do receive adverse comments, then we will publish a document in the **Federal Register** withdrawing this final rule and informing the public that the rule will not take effect. We will then address all public comments in a later final rule.

III. Administrative Requirements

A. Executive Order 12866

The Office of Management and Budget (OMB) has exempted this regulatory action from Executive Order (E.O.) 12866, entitled ''Regulatory Planning and Review.''

B. Executive Order 12875

Under E.O. 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a state, local, or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected state, local, and tribal governments, the nature of their concerns, copies of written communications from the governments, and a statement supporting the need to issue the regulation. In addition, E.O. 12875 requires EPA to develop an effective process permitting elected officials and other representatives of state, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's action would simply extend the deadline for submittal of a plan required by the Clean Air Act; therefore, it will not create a new mandate on state, local or tribal governments. Accordingly, the requirements of section 1(a) of E.O. 12875 do not apply to this rule.

C. Executive Order 13045

Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997), applies to any rule that: (1) Is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an

[1] This extension of the submittal deadline does not affect the submittal dates for the enhanced ozone monitoring program elements that are required for serious ozone nonattainment areas by CAA section 182(c)(1). These dates are already required by regulations at 40 CFR part 58. The extension also does not affect the submittal date for the clean fuel vehicle program required by section 182(c)(4) which is established in section 246(a)(3) of the Act as 1 year from the effective date of the reclassification.

[2] The effective date was subsequently reset to February 13, 1998 because the original final action was not submitted to Congress prior to its original effective date as required by the Administrative Procedures Act. We issued a technical correction to the effective date on February 13, 1998; however, we retained the December 8, 1998 submittal deadline for submittal of the serious area plan.

environmental health or safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, EPA must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it is neither economically significant nor does it involve decisions intended to mitigate environmental health or safety risks.

D. Executive Order 13084

Under E.O. 13084, EPA may not issue a regulation that is not required by statute, that significantly affects or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide to the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of section 3(b) of E.O. 13084 do not apply to this rule.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This action will not have a significant impact on a substantial number of small entities because it simply extends the deadline for the State of Arizona to submit an already-mandated requirement. Because the State of Arizona is not a ''small entity'' under RFA and this action does not create any new requirements, I certify that this action will not have a significant economic impact on a substantial number of small entities.

F. Unfunded Mandates

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (''Unfunded Mandates Act''), signed into law on March 22, 1995, EPA must prepare a budgetary impact statement to accompany any proposed or final rule that includes a Federal mandate that may result in estimated annual costs to State, local, or tribal governments in the aggregate; or to private sector, of $100 million or more. Under Section 205, EPA must select the most cost-effective and least burdensome alternative that achieves the objectives of the rule and is consistent with statutory requirements. Section 203 requires EPA to establish a plan for informing and advising any small governments that may be significantly or uniquely impacted by the rule.

EPA has determined that this action extending the deadline for submittal of an already-required plan does not include a Federal mandate that may result in estimated annual costs of $100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this action.

G. Submission to Congress and the General Accounting Office

Under section 801(a)(1)(A) of the Administrative Procedures Act (APA) as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, EPA submitted a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives and the Comptroller General of the General Accounting Office prior to publication of the rule in today's **Federal Register**. This rule is not a ''major rule'' as defined by section 804(2) of the APA as amended.

H. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 19, 1999. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. See section 307(b)(2).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, ozone.

Date: October 24, 1998.

Felicia Marcus,

Regional Administrator, Region IX.

[FR Doc. 98–29820 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 406

rain Mills Point Source Category

CFR Correction

In title 40 of the Code of Federal Regulations, part 400 to 424, revised as of July 1, 1998, on page 78, in the second column, § 406.22 is printed correctly as follows:

§ 406.22 Effluent limitations guidelines representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available.

Except as provided in §§ 125.30 through 125.32, any existing point source subject to this subpart shall achieve the following effluent limitations representing the degree of effluent reduction attainable by the application of the best practicable control technology currently available (BPT):

Effluent characteristic	Effluent limitations	
	Maximum for any 1 day	Average of daily values for 30 consecutive days shall not exceed—
	Metric units (kilograms per 1,000 kg of corn)	
BOD*5*	0.21	0.07
TSS	0.18	0.06
pH	(1)	(1)
	English units (pounds per 1,000 stdbu of corn)	
BOD*5*	12.0	4.0
TSS	10.5	3.5
pH	(1)	(1)

1 Within the range 6.0 to 9.0.

[39 FR 10513, Mar. 20, 1974, as amended at 60 FR 33936, June 29, 1995]

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Final rule.

SUMMARY: Modified base (1% annual chance) flood elevations are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents.

EFFECTIVE DATES: The effective dates for these modified base flood elevations are indicated on the following table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect for each listed community prior to this date.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of modified base flood elevations for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Associate Director has resolved any appeals resulting from this notification.

The modified base flood elevations are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection.

The modifications are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program.

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities.

These modified elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the National Flood Insurance Program. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
New York: Erie (FEMA Docket No. 7249).	Town of Orchard Park.	December 20, 1997, December 27, 1997, *The Southtowns Citizen.*	Mr. Dennis J. Mill, Supervisor of the Town of Orchard Park, 4295 South Buffalo Street, Orchard Park, New York 14127.	March 27, 1998	360255 B

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: November 10, 1998.

Michael J. Armstrong,

Associate Director for Mitigation.

[FR Doc. 98–31041 Filed 11–19–98; 8:45 am]

BILLING CODE 6718–04–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–7273]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (1% annual chance) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) (FIRMs) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Associate Director reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461.

SUPPLEMENTARY INFORMATION: The modified base flood elevations are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified base flood elevation determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program.

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the National Flood Insurance Program. No regulatory flexibility analysis has been prepared.

Regulatory Classification. This interim rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism. This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform. This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Connecticut: Hartford.	City of Bristol	March 20, 1998, March 27, 1998, *Bristol Press.*	The Honorable Frank N. Nicastrov, Sr., Mayor of the City of Bristol, 111 North Main Street, Bristol, Connecticut 06010.	March 13, 1998	090023 B
Florida: Broward	City of Pompano Beach.	May 22, 1998, May 29, 1998, *Sun-Sentinel.*	The Honorable William F. Griffin, Mayor of the City of Pompano Beach, P.O. Drawer 1300, 100 West Atlantic Boulevard, Pompano Beach, Florida 33060.	April 24, 1998	120055 F

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Orange	Unincorporated Areas.	December 9, 1997, December 16, 1997, *The Orlando Sentinel*.	M. Krishnamurthy, Ph.D., P.E., Manager, Orange County Stormwater, Management Department, 4200 South John Young Parkway, Orlando, Florida 32839.	July 17, 1997	120179 D
Illinois: Cook and Lake.	Village of Barrington.	September 10, 1998, September 17, 1998, *Barrington Courier-Review*.	Mr. Ronald Hamelberg, Village of Barrington President, 206 South Hough Street, Barrington, Illinois 60010.	December 16, 1998.	170057 F
Maine: Knox	Town of South Thomaston.	May 21, 1998, May 28, 1998, *The Courier Gazette*.	Mr. John Spear, First Selectman, Town of South Thomaston, P.O. Box 147, South Thomaston, Maine 04858.	May 13, 1998	230078 B
Minnesota:					
Hennepin	City of Maple Grove.	March 25, 1998, April 1, 1998, *Osseo-Maple Grove Press*.	The Honorable Robert A. Burlingame, Mayor of the City of Maple Grove, P.O. Box 1180, 9401 Fernbrook Lane, Maple Grove, Minnesota 55311–6180.	March 18, 1998	270169 B
Olmsted	Unincorporated Areas.	March 6, 1998, March 13, 1998, *Post-Bulletin*.	Mr. Richard Devlin, Olmsted County Administrator, 151 4th Street, S.E., Rochester, Minnesota 55904.	February 27, 1998	270626 D
Olmsted	City of Rochester	March 6, 1998, March 13, 1998, *Post-Bulletin*.	The Honorable Chuck Caufield, Mayor of the City of Rochester, 201 4th Street, S.E., Rochester, Minnesota 55904–3782.	February 27, 1998	275246
New Jersey: Hunterdon.	Township of Tewksbury.	March 12, 1998, March 19, 1998, *Hunterdon County Democrat*.	Mr. Ralph E. Blakeslee, III, Township Administrator for the Township of Tewksbury, 169 Old Turnpike Road, Califon, New Jersey 07830.	June 17, 1998	340516 B
Ohio:					
Lorain	City of Avon	October 14, 1998, October 21, 1998, *The Morning Journal*.	The Honorable James A. Smith, Mayor of the City of Avon, 36080 Chester Road, Avon, Ohio 44011–1588.	October 6, 1998 ...	390348 C
Franklin	City of Grove City	October 7, 1998, October 14, 1998, *Grove City Record*.	The Honorable Cheryl L. Grossman, Mayor of the City of Grove City, P.O. Box 427, Grove City, Ohio 43123–0427.	September 28, 1998.	390173 G
Lorain	City of North Ridgeville.	March 18, 1998, March 25, 1998, *The Press & Light*.	The Honorable Deanna C. Hill, Mayor of the City of North Ridgeville, 7307 Avon Belden Road, North Ridgeville, Ohio 44039.	March 9, 1998	390352 C
Tennessee:					
Shelby	City of Bartlett	October 2, 1998, October 9, 1998, *The Commercial Appeal*.	The Honorable Bobby K. Flaherty, Mayor of the City of Bartlett, 6400 Stage Road, Bartlett, Tennessee 38134.	September 25, 1998.	470175 E
Haywood	City of Brownsville	August 6, 1998, August 13, 1998, *Brownsville States-Graphic*.	The Honorable F. Webb Banks, Mayor of the City of Brownsville, 111 North Washington Street, Brownsville, Tennessee 38012.	July 30, 1998	470087 C
Shelby	Unincorporated Areas.	October 2, 1998, October 9, 1998, *The Commercial Appeal*.	Mr. Jim Kelley, Shelby County Chief Administrative Officer, 160 North Main Street, Suite 850, Memphis, Tennessee 38103.	September 25, 1998.	470214 E

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: November 10, 1998.

Michael J. Armstrong,

Associate Director for Mitigation.

[FR Doc. 98–31040 Filed 11–19–98; 8:45 am]

BILLING CODE 6718–04–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Base (1% annual chance) flood elevations and modified base flood elevations are made final for the communities listed below. The base flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the

National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the maps are available for inspection as indicated on the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA or Agency) makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the **Federal Register**.

This final rule is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67.

The Agency has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and Flood Insurance Rate Map available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the National Flood Insurance Program. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows:

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
FLORIDA	
Leesburg (City), Lake County (FEMA Docket No. 7255)	
Lake Hollywood:	
Entire shoreline	*77
Ponding Area K1–1:	
Entire shoreline	*69
Ponding Area K1–2B:	
Entire shoreline	*74
Ponding Area K1–2C:	
Entire shoreline	*73
Ponding Area K1–2D:	
Entire shoreline	*73
Maps available for inspection at the City of Leesburg Engineering Department, 501 West Meadow Street, Leesburg, Florida.	
GEORGIA	
Augusta (City) (FEMA Docket No. 7255)	
Oates Creek:	
Approximately 50 feet upstream of Fort Gordon Highway	*125
Approximately 30 feet downstream of Olive Road	*146
Oates Creek Tributary No. 1:	
At confluence with Oates Creek	*144
At Olive Road	*154
Rocky Creek:	
Just downstream of New Savannah Road	*125
Approximately 800 feet downstream of Old Savannah Road	*130
Butler Creek:	
Just downstream of Windsor Spring Road	*188
Just upstream of Windsor Spring Road	*190
Rocky Creek Tributary No. 2:	
At confluence with Rocky Creek	*128
Approximately 0.3 mile upstream of confluence with Rocky Creek	*128
Maps available for inspection at the Augusta-Richmond County Planning Department, 525 Telfair Street, Augusta, Georgia.	
ILLINOIS	
Glenview (Village), Cook County (FEMA Docket No. 7231)	
South Navy Ditch:	
At confluence with Chicago River, North Branch, West Fork	*628
Approximately 100 feet downstream of Soo Line Railroad	*628
Des Plaines River:	
Upstream side of Central Road	*637
Approximately 0.7 mile upstream of Central Road	*637
Chicago River, North Branch, West Fork:	
At the downstream corporate limits	*621
At the upstream corporate limits	*631
Chicago River, North Branch:	
Approximately 300 feet upstream of corporate limits	*624
At Central Road	*621
Maps available for inspection at the Glenview Village Hall, 1225 Waukegan Road, Glenview, Illinois.	

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
NEW JERSEY	
Beach Haven (Borough), Ocean County (FEMA Docket No. 7243)	
Atlantic Ocean:	
At intersection of Beach Avenue and 6th Street	*8
Approximately 650 feet southeast of the intersection of Atlantic Avenue and Taylor Avenue	*13
Approximately 50 feet east of intersection of 6th Street and Atlantic Avenue	#1
Little Egg Harbor:	
Entire shoreline within community	*10
Maps available for inspection at the Borough Zoning Office, Beach Haven Municipal Building, 300 Engleside Avenue, Beach Haven, New Jersey.	
Barnegat Light (Borough), Ocean County (FEMA Docket No. 7243)	
Atlantic Ocean:	
Approximately 1,000 feet southeast of intersection of East 26th Street and Long Beach Boulevard	*13
East side of Long Beach Boulevard	#1
Barnegat Bay:	
At the intersection of Bayview Avenue and 10th Street	*5
Maps available for inspection at the Borough Hall, 10 West 10th Street, Barnegat Light, New Jersey.	
Harvey Cedars (Borough), Ocean County (FEMA Docket No. 7243)	
Atlantic Ocean:	
Approximately 650 feet southeast of intersection of Long Beach Boulevard and 68th Street	*13
Approximately 250 feet southeast of intersection of Long Beach Boulevard and 68th Street	#1
Manahawkin Bay:	
Approximately 500 feet northwest of intersection of Suffolk Place and Buckingham Avenue	*8
Maps available for inspection at the Borough Municipal Building, 7606 Long Beach Boulevard, Harvey Cedars, New Jersey.	
Long Beach (Town), Ocean County (FEMA Docket No. 7243)	
Atlantic Ocean:	
At intersection of Coast Avenue and Arts Lane	#1
At intersection of 127th and Ocean Avenue	#1
At intersection of Beach Avenue and Oceanview Drive	8
Approximately 400 feet east of intersection of Coast Avenue and Arts Lane	*13
Barnegat Bay:	
Approximately 150 feet west of intersection of Bayview and Panorama Drives	*5
At the intersection of Dusty Miller Drive and Tidal Drive	*5
Approximately 100 feet northwest of the intersection of Sandy Cove Lane and Long Beach Boulevard	*5
Manahawkin Bay:	
At intersection of Roxie Avenue and Long Beach Boulevard	*7
Little Egg Harbor:	
Entire shoreline of Shelter Island	*10
Maps available for inspection at the Long Beach Township Zoning Office, James J. Mancini Administration Building, 6805 Long Beach Boulevard, Long Beach, New Jersey.	
Ship Bottom (Borough), Ocean County (FEMA Docket No. 7243)	
Atlantic Ocean:	
Approximately 1,000 feet southeast of the intersection of Long Beach Boulevard and 7th Street	*13
Approximately 400 feet southeast of the intersection of Long Beach Boulevard and 7th Street	#1
Maps available for inspection at the Borough Clerk's Office, Borough Hall, 1621 Long Beach Boulevard, Ship Bottom, New Jersey.	
Surf City (Borough), Ocean County (FEMA Docket No. 7243)	
Atlantic Ocean:	
Approximately 400 feet southeast of intersection of Ocean Terrace and 17th Street	*13
West side of Ocean Terrace	#1
Maps available for inspection at the Borough Municipal Clerk's Office, Borough Hall, 813 Long Beach Boulevard, Surf City, New Jersey.	
NEW YORK	
Barneveld (Village), Oneida County (FEMA Docket No. 7259)	
Cincinnati Creek:	
Approximately 1,350 feet downstream of Park Avenue	*762
Approximately 1,650 feet upstream of Park Avenue	*780
Steuben Creek:	
At confluence with Cincinnati Creek	*772
Approximately 230 feet upstream of State Route 365	*778
Maps available for inspection at the Village of Barneveld Office, 8520 Old Poland Road, Barneveld, New York.	
NORTH CAROLINA	
Hickory (City), Burke and Catawba Counties (FEMA Docket Nos. 7231 and 7251)	
Lake Hickory:	
At downstream corporate limits	*935
At NC 127	*936
Snow Creek:	
Approximately 120 feet downstream of a private drive	*957
Approximately 30 feet upstream of a private drive	*959
Maps available for inspection at the City of Hickory Planning Office, 76 North Center Street, Hickory, North Carolina.	
OHIO	
Columbus (City), Delaware County (FEMA Docket No. 7251)	
Olentangy River:	
Approximately 0.6 mile upstream of confluence of Fisher Run	*764
Approximately 0.8 mile upstream of Henderson Road	*742
Maps available for inspection at the City of Columbus Development Regulation Division, 1250 Fairwood Avenue, Columbus, Ohio.	
Delaware County (Unincorporated Areas) (FEMA Docket No. 7251)	
Bartholomew Run:	
Approximately 750 feet upstream of State Route 315	*780
Approximately 75 feet upstream of CSX Transportation	*921
Big Run:	
At confluence with Weeping Rock Run	*809
Approximately 100 feet upstream of Hyatts Road	*909
Big Walnut Creek:	
At Sunbury Road	*902
Approximately 215 feet upstream of U.S. Highway 36	*996
Deep Run:	
At confluence with Olentangy River	*777
Approximately 60 feet upstream of U.S. Highway 23	*935
Fulton Creek:	
At a point just upstream of Fulton Creek Road	*891
At upstream county boundary	*923
Lewis Center Run:	
At confluence with Alum Creek	*826
Approximately 100 feet upstream of Big Walnut Road	*863

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
Lick Run:	
At confluence with Olentangy River	*783
Approximately 50 feet upstream of CSX Transportation	*922
Little Walnut Creek:	
At downstream side of U.S. Highway 36	*915
At Carters Corner Road	*939
Olentangy River:	
At the downstream county boundary	*768
Approximately 4,000 feet downstream of U.S. Highway 23	*820
Reed Run:	
At confluence with Olentangy River	*790
At CSX Transportation	*918
Weeping Rock Run:	
At confluence with Olentangy River	*792
At North Road	*920
Wildcat Run:	
At confluence with Reed Run	*803
Approximately 40 feet upstream of CSX Transportation	*923
Tylers Run:	
At confluence with Bartholomew Run	*826
Approximately 100 feet downstream of Liberty Street	*884
Spring Run:	
Approximately 500 feet downstream of Maxtown Road	*892
At Maxtown Road	*893
Maps available for inspection at the Delaware County Floodplain Administrator's Office, 50 Channing Street, Delaware, Ohio.	
Franklin County (Unincorporated Areas) (FEMA Docket No. 7251)	
Olentangy River:	
At upstream county boundary	*768
Approximately 0.9 mile upstream of Henderson Road	*742
Maps available for inspection at the Franklin County Emergency Management Office, 756 Harmon Avenue, Columbus, Ohio.	
Galena (Village), Delaware County (FEMA Docket No. 7251)	
Big Walnut Creek:	
At Sunbury Road	*902
At a point approximately 1,000 feet downstream of Abandoned Railroad bridge	*908
Maps available for inspection at the Village of Galena Municipal Building, 9 West Columbus Street, Galena, Ohio.	
Ostrander (Village), Delaware County (FEMA Docket No. 7251)	
Blues Creek:	
Approximately 900 feet downstream of Penn Road (downstream corporate limits)	*908
Approximately 200 feet downstream of Ostrander Road	*914
Maps available for inspection at the Jacob C. Ostrander Community Center, South Main Street, Ostrander, Ohio.	
Powell (Village), Delaware County (FEMA Docket No. 7251)	
Olentangy River:	
At downstream corporate limit	*776
At upstream corporate limit	*777
Retreat Run:	
At confluence with Olentangy River	*776
Approximately 25 feet downstream of State Route 315	*776
Maps available for inspection at the Village of Powell Municipal Building, 260 Village Park Drive, Powell, Ohio.	
Riverlea (Village), Franklin County (FEMA Docket No. 7251)	
Olentangy River:	
Approximately 600 feet upstream of confluence of Rush Run	*748
Approximately 0.5 mile upstream of confluence of Rush Run	*750
Maps available for inspection at the Mayor's Office, 301 West Riverglen Drive, Worthington, Ohio.	
Sunbury (Village), Delaware County (FEMA Docket No. 7251)	
Big Walnut Creek:	
At confluence of Prairie Run	*926
At a point approximately 150 feet downstream of U.S. Route 36	*994
Maps available for inspection at the Village of Sunbury Building Department, 37 East Granville Street, Sunbury, Ohio.	
Worthington (City), Franklin County (FEMA Docket No. 7251)	
Olentangy River:	
Approximately 400 feet downstream of Interstate 270	*760
Approximately 700 feet downstream of confluence of Rush Run	*746
Maps available for inspection at the Worthington City Engineer's Office, 380 Highland Avenue, Worthington, Ohio.	

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: November 10, 1998.

Michael J. Armstrong,

Associate Director for Mitigation.

[FR Doc. 98–31043 Filed 11–19–98; 8:45 am]

BILLING CODE 6718–04–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 206

RIN 3067–AC89

Disaster Assistance; Redesign of Public Assistance Project Administration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim final rule.

SUMMARY: We have redesigned the Public Assistance Disaster Grant Program to provide money to applicants more quickly and to make the application process simpler than before. This rule reflects changes needed to put the new Public Assistance Program into effect.

DATES: Effective Date: This rule is effective on November 20, 1998.

Comments: We invite your comments on the changes to the rule and your recommendations for additional changes to it on or before January 4, 1999.

ADDRESSES: Please send your comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, room 840, 500 C Street SW., Washington, DC 20472, (telefax) (202) 646–4536, or (email) *rules@fema.gov.*

FOR FURTHER INFORMATION CONTACT: Melissa M. Howard, Ph.D., Federal Emergency Management Agency, room 713, 500 C Street SW., Washington DC 20472, (202) 646–4240, or (email) *melissa.howard@fema.gov.*

SUPPLEMENTARY INFORMATION:

What does the redesigned program do? The redesigned program emphasizes better, more personal customer service, improved communications, reallocated responsibilities, more efficient and consistent program delivery, and a faster, simpler system for obtaining funding than under our current regulations. As we announced in our February 4, 1998 **Federal Register** notice, 63 FR 5804, we field tested the new system from March 1, 1998 to August 31, 1998. While we are making most of our improvements through internal changes to our procedures, some of the improvements require

amendments to the governing regulations. This publication makes those amendments.

What are the basic components of the public assistance grant process? The grant process was redesigned around its four pillars: People, Process, Policy and Performance.

People—The most important component of the redesigned program is People. The success of the program depends on all the people involved in the process, both those who apply for grants and those who are responsible for awarding grants. People who understand the provisions of the program and are willing to work cooperatively in disaster recovery efforts speed the process and make the redesigned program possible. Therefore, to ensure the highest level of professionalism and skill among FEMA staff, we have committed ourselves to program-wide training, to a credentials program, and to a greatly expanded program for sharing information.

Process—We base the program on a partnership among FEMA, the States and local officials. FEMA's role is to provide guidance early in the recovery process, and in some cases, before the disaster occurs. This is a change from our previous focus on inspection and enforcement. In our new role we will provide more information about the program before the disaster strikes and will provide more technical assistance in the development of damage descriptions and cost estimates after the disaster.

The States' role is essentially unchanged from the existing program. As Grantee, the State remains responsible for administering the Federal grant.

The role of local governments and eligible private nonprofit organizations changes with their taking more control in meeting their own needs and speeding their own recovery. For example, those applicants who are able to do so may prepare damage descriptions and cost estimates for small projects. We will continue to help other applicants to prepare their damage descriptions and costs estimates.

Policy—The redesigned program does not change program eligibility, but it does require changes to regulatory, policy and procedural program documents. The changes streamline, simplify and clarify program operations. They also make source documents readily available to those applying for grants and to those who administer the grants.

Performance—The people, policies, and processes that form the foundation of the redesigned program will enhance program performance. Evaluation of that performance is an essential part of the redesigned program.

Where can you find additional information? You can find additional descriptive information on the redesigned program on our website (http://www.fema.gov.). At our home page click on Disaster Assistance, then click on Public Assistance, and choose from the menu under the Public Assistance Program.

What changes are we making to the rule? Specific changes to the regulations rename documents, define terms, adjust responsibilities, and edit the rule in a way that we hope makes it easier to read and to understand.

(1) Throughout the text, ''Disaster Survey Report'' or ''DSR'' is renamed ''Project Worksheet.''

(2) We edited § 206.200(b) to read more clearly than before.

(3) We redefined ''project'' in § 206.201(i) to reflect our new policy.

(4) In § 206.202(b) we removed ''damage survey activities,'' because inspection teams will not exist as before. We also added language about the States' roles in supporting large project identification activities.

(5) In § 206.202(c) we changed ''Notice of Interest'' to ''Request for Public Assistance.''

(6) We removed the requirement for a FEMA/State/local inspection team in § 206.202(d)(1), and changed the starting date of the ''60 day'' period from the date of the initial visit to the date of the first substantive meeting.

(7) We state in § 206.202(d)(2) that we will not approve a Project Worksheet for less than $1,000 and we replace ''site'' with ''project.''

(8) In § 206.202(e) we keep our obligation to explain any delays, but remove the requirement for written explanation of any delay.

(9) Because the applicant will now prepare the Project Worksheet with possible help from the State, § 206.228(a)(2) changes the description of State's responsibility from ''* * * preparation of damage survey reports * * *'' to ''* * * develop and validate Project Worksheets * * *.''

(10) We anticipate that the form number assigned for the ''Damage Survey Report'' (FEMA Form 90–91) will be used for the ''Project Worksheet'' and that the form number assigned for the ''Notice of Interest'' (FEMA Form 90–49) will be used for ''Request for Assistance.'' If we assign new form numbers, we will make the change when we publish the final rule.

Administrative Procedure Act Determination

We are publishing this interim final rule without opportunity for prior public comment under the Administrative Procedure Act, 5 U.S.C. 553, having determined that a comment period would be unnecessary, impractical, and contrary to the public interest. This interim final rule does not contain any significant, substantive changes from previous regulations, but reflects changes to internal procedures under which we will process public assistance applications more quickly and simply than before.

Procedures affecting public assistance applications remain substantially unchanged. The procedural changes do not affect the rights of applicants, and primarily affect how we will administer the program. In order to implement the programs for assessments made for FY 1999 and beyond, we need to modify and publish its regulations. We invite public comments on the interim final rule. We will take into account any comments we receive when we publish the final rule.

As Director I determine that good cause exists and that it is in the public interest to issue this interim final rule without opportunity for prior public comment.

National Environmental Policy Act

Our regulations categorically exclude this rule from the preparation of environmental impact statements and environmental assessments as an administrative action in support of normal day-to-day grant activities. We have not prepared an environmental assessment or an environmental impact statement.

Regulatory Flexibility Act

We do not expect this rule (1) to affect adversely the availability of disaster assistance funding to small entities, (2) to have significant secondary or incidental effects on a substantial number of small entities, or (3) to create any additional burden on small entities.

As Director I certify that this rule is not a major rule under Executive Order 12291 and that the rule will not have significant impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act.

Paperwork Reduction Act

This rule does not involve any collection of information for the purposes of the Paperwork Reduction Act.

Executive Order 12612, Federalism

In publishing this rule, we considered the President's Executive Order 12612 on Federalism. This rule makes no changes in the division of governmental responsibilities between the Federal government and the States. Grant administration procedures under 44 CFR Part 13, Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments, remain the same. We have not prepared a Federalism assessment.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of section 2(b)(2) of Executive Order 12778, Civil Justice Reform, dated October 25, 1991, 3 CFR, 1991 Comp., p. 359.

Congressional Review of Agency Rulemaking

We have sent this final rule to the Congress and to the General Accounting Office under the Congressional Review of Agency Rulemaking Act, 5 U.S.C. 801 *et seq.* The rule is not a ''major rule'' within the meaning of that Act. It does not result in nor is it likely to result in an annual effect on the economy of $100,000,000 or more. It will not result in a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. It will not have ''significant adverse effects'' on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises.

This final rule is exempt (1) from the requirements of the Regulatory Flexibility Act, as certified previously, and (2) from the Paperwork Reduction Act.

This rule is not an unfunded Federal mandate within the meaning of the Unfunded Mandates Reform Act of 1995, Pub. L.104–4. The rule does not meet the $100,000,000 threshold of that Act, and any enforceable duties are imposed as a condition of Federal assistance or a duty arising from participation in a voluntary Federal program.

List of Subjects in 44 CFR Part 206

Disaster assistance, Public assistance.

Accordingly, 44 CFR part 206 is amended as follows:

PART 206—[AMENDED]

1. The authority citation for part 206 continues to read as follows:

Authority: The Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.*; Reorganization Plan No. 3 of 1978, 43 FR 41943, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376; E.O. 12148, 44 FR 43239, 3 CFR, 1979 Comp., p. 412; and E.O. 12673, 54 FR 12571, 3 CFR, 1989 Comp., p. 214.

2. Revise § 206.200(b) to read as follows:

§ 206.200 General.

* * * * *

(b) *What policies apply to FEMA public assistance grants?* (1) The Stafford Act requires that we deliver eligible assistance as quickly and efficiently as possible consistent with Federal laws and regulations. We expect you, as State Grantee, to adhere to Stafford Act requirements and to the regulations in this part when you administer our public assistance grants.

(2) The regulations entitled ''Uniform Requirements for Grants and Cooperative Agreements to State and Local Governments,'' published at 44 CFR part 13, place requirements on you and give you discretion to administer federal programs under your own procedures. We expect you, as State grantee, to:

(i) Inform subgrantees about the status of their applications, including notifications of our approvals of Project Worksheets and our estimates of when we will make payments;

(ii) Pay the full amounts due to subgrantees as soon as practicable after we approve payment, including your State contribution required in the FEMA-State Agreement; and

(iii) Pay your State contribution consistent with State laws.

3. Revise the definitions of *project* and *project approval* in § 206.201(i) and (j) to read as follows:

§ 206.201 Definitions.

* * * * *

(i) A *project* is a logical grouping of work required as a result of the declared major disaster or emergency.

(1) We must approve a scope of eligible work and an itemized cost estimate before funding a project.

(2) A project may include eligible work at several sites.

(j) *Project approval* means the process in which the Regional Director, or designee, reviews and signs an approval of work and costs on a Project Worksheet or on a batch of Project Worksheets. Such approval is also an obligation of funds to the Grantee.

* * * * *

4. Revise § 206.202 to read as follows:

§ 206.202 Application procedures.

(a) *General.* This section describes the policies and procedures we use to process public assistance grants to States. Under this section you, the State, are the Grantee. As Grantee you are responsible for processing subgrants to applicants under 44 CFR parts 13, 14, and 206, and under your own policies and procedures.

(b) *Grantee.* You are the grant administrator for all funds provided under the Public Assistance grant program. Your responsibilities under this section include:

(1) Providing technical advice and assistance to eligible subgrantees;

(2) Providing State support for project identification activities;

(3) Ensuring that all potential applicants are aware of available public assistance; and

(4) Submitting documents necessary for the award of grants.

(c) *Request for public assistance (Request).* You, the Grantee, must send a completed Request (FEMA Form 90–49) to the Regional Director for each applicant who requests public assistance. You must send Requests to the Regional Director within 30 days after designation of the area where the damage occurred.

(d) *Project Worksheets.* (1) An applicant's authorized local representative is responsible for representing the applicant and for ensuring that the applicant has identified all eligible work and submitted all costs for disaster-related damages for funding.

(i) We or the applicant will prepare a Project Worksheet (FEMA Form 90–91) for each project. The Project Worksheet must identify the eligible scope of work and must include a quantitative estimate for the eligible work.

(ii) The applicant will have 60 days following its first meeting with us to identify and to report damage to us.

(2) When the estimated cost of work on a project is less than $1,000, that work is not eligible and we will not approve a Project Worksheet for the project. Periodically we will review this minimum approval amount for a Project Worksheet and, if needed, will adjust the amount by regulation.

(e) *Grant approval.* (1) When the applicant submits the Project Worksheets, we will have 45 days to obligate Federal funds. If we have a delay beyond 45 days we will explain the delay to you.

(2) Before we obligate any funds you, the Grantee, must complete and send to the Regional Director a Standard Form (SF) 424, Application for Federal Assistance, and an SF 424D, Assurances

for Construction Programs. After we receive the SF 424 and SF 424D, the Regional Director will obligate funds to you based on the approved Project Worksheets. You will then approve subgrants based on the Project Worksheets approved for each applicant.

5. Revise § 206.228(a)(2)(i) to read as follows:

§ 206.228 Allowable costs.

* * * * *

(a) * * *

(1) * * *

(2) *Statutory Administrative Costs*—(i) *Grantee.* Under section 406(f)(2) of the Stafford Act, we will pay you, the State, an allowance to cover the extraordinary costs that you incur to develop and validate Project Worksheets, to prepare final inspection reports, project applications, final audits, and to make related field inspections by State employees. Eligible costs include overtime pay and per diem and travel expenses, but do not include regular time for your State employees. The allowance to you will be based on the following percentages of the total amount of Federal assistance that we provide for all subgrantees in the State under sections 403, 406, 407, 502, and 503 of the Act:

* * * * *

Dated: November 13, 1998.

James L. Witt,

Director.

[FR Doc. 98–31044 Filed 11–19–98; 8:45 am]

BILLING CODE 6718–02–P

DEPARTMENT OF DEFENSE

48 CFR Parts 209, 213, 219, 225, 231, 235, 236, 252, and 253

Defense Federal Acquisition Regulation Supplement; Adoption of Interim Rules as Final Rules Without Change

AGENCY: Department of Defense (DoD).

ACTION: Final rules.

SUMMARY: The Director of Defense Procurement is adopting as final, without change, eight interim rules that amended the Defense Federal Acquisition Regulation Supplement (DFARS). The rules pertain to contractor responsibility, awards to small disadvantaged business concerns, small business subcontracting plans, domestic source restrictions, restructuring costs, research and development contracting, and construction in foreign countries.

EFFECTIVE DATE: November 20, 1998.

FOR FURTHER INFORMATION CONTACT:

Ms. Michelle Peterson, (703) 602–0131.

SUPPLEMENTARY INFORMATION:

A. Background

The following is a summary of the eight interim rules that are adopted as final without change. DoD published the interim rules in the **Federal Register** for public comment and considered all comments received.

List of Firms Not Eligible for Defense Contracts (DFARS Case 97–D325) (63 FR 14836, March 27, 1998)

This rule amends DFARS Parts 209 and 252 to implement Section 843 of the National Defense Authorization Act for Fiscal Year 1998 (Public Law 105–85). Section 843 requires that the Secretary of Defense maintain a list of all firms that the Secretary has identified as being subject to a prohibition on contract award due to ownership or control of the firm by the government of a terrorist country; and that DoD contractors be prohibited from entering into subcontracts with firms on the list unless there is a compelling reason to do so.

Direct Award of 8(a) Contracts (DFARS Case 98–D011) (63 FR 33586, June 19, 1998)

This rule amends DFARS Parts 213, 219, 252, and 253 to implement a Memorandum of Understanding (MOU) dated May 6, 1998, between the Small Business Administration (SBA) and DoD. The MOU streamlines the processing procedures for contract awards under SBA's 8(a) Program by authorizing DoD to award contracts directly to 8(a) concerns.

Comprehensive Subcontracting Plans (DFARS Case 97–D323) (63 FR 14640, March 26, 1998)

This rule amends DFARS 219.702 to reflect revisions made to the DoD Test Program for Negotiation of Comprehensive Small Business Subcontracting Plans, as required by Section 822 of the National Defense Authorization Act for Fiscal Year 1998 (Public Law 105–85). Section 822 extends, from September 30, 1998, to September 30, 2000, the expiration date for the test program; and provides for use of comprehensive subcontracting plans by participating contractors that are performing as subcontractors under DoD contracts.

Waiver of 10 U.S.C. 2534—United Kingdom (DFARS Case 98–D016) (63 FR 43887, August 17, 1998)

This rule amends DFARS Subpart 225.70 and the clauses at DFARS 252.225–7016 and 252.225–7029 to implement a waiver of the domestic source restrictions of 10 U.S.C. 2534(a) for certain items manufactured in the United Kingdom. The waiver was signed by the Under Secretary of Defense (Acquisition and Technology) on June 19, 1998, and became effective on August 4, 1998.

Allowability of Costs for Restructuring Bonuses (DFARS Case 97–D312) (62 FR 63035, November 26, 1997)

This rule amends DFARS 231.205–6 to implement Section 8083 of the National Defense Appropriations Act for Fiscal Year 1998 (Public Law 105–56). Section 8083 prohibits the use of fiscal year 1998 funds to reimburse a contractor for costs paid by the contractor to an employee for a bonus or other payment in excess of the normal salary paid by the contractor to the employee, when such payment is part of restructuring costs associated with a business combination.

Restructuring Costs (DFARS Case 97–D313) (63 FR 7308, February 13, 1998)

This rule amends DFARS 231.205–70 to implement Section 8092 of the National Defense Appropriations Act for Fiscal Year 1998 (Public Law 105–56) and Section 804 of the National Defense Authorization Act for Fiscal Year 1998 (Public Law 105–85). Sections 8092 and 804 restrict the reimbursement of restructuring costs associated with a business combination undertaken by a defense contractor unless certain conditions are met.

Streamlined Research and Development Contracting (DFARS Case 97–D002) (63 FR 34605, June 25, 1998)

This rule revises DFARS Subpart 235.70 to implement streamlined solicitation and contracting procedures for research and development acquisitions. The procedures use a standard solicitation and contract format, and use the World Wide Web to disseminate the standard format and publish the resulting solicitations.

Construction in Foreign Countries (DFARS Case 97–D307) (63 FR 11522, March 9, 1998)

This rule amends DFARS Part 236 and adds a new provision at 252.236–7012 to implement Section 112 of the Military Construction Appropriations Act for Fiscal Year 1998 (Public Law 105–45). Section 112 provides that no military construction appropriations may be used to award, to a foreign contractor, any contract estimated to exceed $1,000,000 for military construction in the United States territories and possessions in the Pacific

and on Kwajalein Atoll, or in countries bordering the Arabian Gulf, except for: (1) Contract awards for which the lowest responsive and responsible bid of a United States firm exceeds the lowest responsive and responsible bid of a foreign firm by more than 20 percent, and (2) contract awards for military construction on Kwajalein Atoll for which the lowest responsive and responsible bid is submitted by a Marshallese firm.

B. Regulatory Flexibility Act

DoD certifies that these final rules will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, et seq., because:

List of Firms Not Eligible for Defense Contracts (DFARS Case 97–D325)—Few small entities are believed to subcontract with firms that are owned or controlled by the government of a terrorist country.

Direct Award of 8(a) Contracts (DFARS Case 98–D011)—The rule only affects the administrative procedures used to award 8(a) contracts.

Comprehensive Subcontracting Plans (DFARS Case 97–D323)—Small businesses are exempt from subcontracting plan requirements, and the rule does not change the obligation of large business concerns to maximize subcontracting opportunities for small business concerns.

Waiver of 10 U.S.C. 2534—United Kingdom (DFARS Case 98–D016)—There are no known small business manufacturers of the restricted air circuit breakers; defense appropriations acts presently impose domestic source restrictions on the acquisition of totally enclosed lifeboats and noncommercial ball and roller bearings; and the restrictions of 10 U.S.C. 2534(a) do not apply to acquisitions of commercial items incorporating ball or roller bearings.

Restructuring Costs (DFARS Case 97–D313) and Allowability of Costs for Restructuring Bonuses (DFARS Case 97–D312)—Most contracts awarded to small entities use simplified acquisition procedures or are awarded on a competitive fixed-priced basis, and do not require application of the cost principles contained in these rules.

Streamlined Research and Development Contracting (DFARS Case 97–D002)—The rule merely provides an implementation of electronic contracting procedures already authorized by the FAR.

Construction in Foreign Countries (DFARS Case 97–D307)—The DFARS changes contained in this rule apply only to contracts for military construction on Kawjalein Atoll that are estimated to exceed $1,000,000; DoD awards approximately two such contracts annually.

C. Paperwork Reduction Act

The Office of Management and Budget (OMB) approved the information collection requirements associated with DFARS Case 97–D307, Construction in Foreign Countries, for use through August 31, 2001, under OMB Control Number 0704–0255. The other rules do not contain any information collection requirements that require the approval of OMB under 44 U.S.C. 3501, *et seq.*

List of Subjects in 48 CFR Parts 209, 213, 219, 225, 231, 235, 236, 252, and 253

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Interim Rules Adopted as Final Without Change

PART 209—CONTRACTOR QUALIFICATIONS, AND PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Accordingly, the interim rule amending 48 CFR parts 209 and 252, which was published at 63 FR 14836 on March 27, 1998, is adopted as a final rule without change.

PART 213—SIMPLIFIED ACQUISITION PROCEDURES, PART 219—SMALL BUSINESS PROGRAMS, PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES, AND PART 253—FORMS

Accordingly, the interim rule amending 48 CFR parts 213, 219, 252, and 253, which was published at 63 FR 33586 on June 19, 1998, is adopted as a final rule without change.

PART 219—SMALL BUSINESS PROGRAMS

Accordingly, the interim rule amending 48 CFR part 219, which was published at 63 FR 14640 on March 26, 1998, is adopted as a final rule without change.

PART 225—FOREIGN ACQUISITION, AND PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Accordingly, the interim rule amending 48 CFR parts 225 and 252, which was published at 63 FR 43887 on August 17, 1998, is adopted as a final rule without change.

PART 231—CONTRACT COST PRINCIPLES AND PROCEDURES

Accordingly, the interim rule amending 48 CFR part 231, which was published at 62 FR 63035 on November 26, 1997, is adopted as a final rule without change.

PART 231—CONTRACT COST PRINCIPLES AND PROCEDURES

Accordingly, the interim rule amending 48 CFR part 231, which was published at 63 FR 7308 on February 13, 1998, is adopted as a final rule without change.

PART 235—RESEARCH AND DEVELOPMENT CONTRACTING

Accordingly, the interim rule amending 48 CFR part 235, which was published at 63 FR 34605 on June 25, 1998, is adopted as a final rule without change.

PART 236—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS, AND PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

Accordingly, the interim rule amending 48 CFR parts 236 and 252 at sections 236.102, 236.274, 236.570, 252.236–7010, and 252.236–7012, which was published at 63 FR 11522 on March 9, 1998, is adopted as a final rule without change.

[FR Doc. 98–31038 Filed 11–19–98; 8:45 am]
BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

48 CFR Parts 215, 217, 219, 226, 236, 252, and Appendix I to Chapter 2

[DFARS Case 98–D021]

Defense Federal Acquisition Regulation Supplement; Reform of Affirmative Action in Federal Procurement, Part II

AGENCY: Department of Defense (DoD).

ACTION: Interim rule with request for comments.

SUMMARY: The Director of Defense Procurement has issued an interim rule amending the Defense Federal Acquisition Regulation Supplement (DFARS) guidance concerning programs for small disadvantaged business (SDB) concerns. These amendments conform to a Department of Justice (DoJ) proposal to reform affirmative action in Federal procurement, and are consistent with the changes made to the Federal Acquisition Regulation (FAR) in Federal

Acquisition Circular (FAC) 97–07. DoJ's proposal is designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand Constructors, Inc.* v. *Pena,* 115 S. Ct. 2097 (1995).

DATES: *Effective Date:* January 1, 1999.

Applicability Date: The policies, provisions, and clauses of this interim rule are effective for all solicitations issued on or after January 1, 1999, and all Mentor-Protégé agreements entered into on or after January 1, 1999.

Comment Date: Comments on the interim rule should be submitted in writing to the address shown below on or before January 19, 1999, to be considered in the formulation of the final rule.

ADDRESSES: Interested parties should submit written comments to: Defense Acquisition Regulations Council, Attn: Ms. Susan Schneider, PDUSD(A&T)DP(DAR), IMD 3D139, 3062 Defense Pentagon, Washington, DC 20301–3062, telefax (703) 602–0350.

E-mail comments submitted over the Internet should be addressed to: dfars@acq.osd.mil.

Please cite DFARS Case 98–D021 in all correspondence related to this issue. E-mail comments should cite DFARS Case 98–D021 in the subject line.

FOR FURTHER INFORMATION CONTACT: Ms. Susan Schneider, PDUSD(A&T)DP(DAR), (703) 602–0131, or Mr. Mike Sipple, PDUSD(A&T)DP(CPA), (703) 695–8567. Please cite DFARS Case 98–D021.

SUPPLEMENTARY INFORMATION:

A. Background

In *Adarand,* the Supreme Court extended strict judicial scrutiny to Federal affirmative action programs that use racial or ethnic criteria as a basis for decisionmaking. In procurement, this means that any use of race in the decision to award a contract is subject to strict scrutiny. Under strict scrutiny, any Federal programs that make race a basis for contract decisionmaking must be narrowly tailored to serve a compelling Government interest.

DoJ developed a proposed structure to reform affirmative action in Federal procurement designed to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand*. the DoJ proposal was published for public notice and comment (61 FR 26042, May 23, 1996). DoJ issued a notice that provided a response to the public comments (62 FR 25648, May 9, 1997). To implement the DoJ concept, two interim FAR rules and an interim DFARS rule were issued: FAC 97–06, effective October 1, 1998, implements a price evaluation adjustment for SDB concerns (63 FR 35719, June 30, 1998); FAC 97–07, effective January 1, 1999, implements an SDB participation program (63 FR 36120, July 1, 1998); and the rule published on August 6, 1998 (63 FR 41972), effective October 1, 1998, conforms the DFARS to FAC 97–06. This interim rule contains the revisions necessary to conform the DFARS to the interim FAR rule in FAC 97–07, and to the DoJ proposal implemented by the FAR rule.

B. Regulatory Flexibility Act

This interim rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because most of the changes merely conform the DFARS to the FAR rule in FAC 97–07. Two source selection considerations for SDB concerns currently in the DFARS, but not in the FAR, are amended by this rule to conform to the DoJ model: Leader company contracting (DFARS 217.401); and architect-engineer (A–E) services (DFARS 236.602). These two changes are not expected to have a significant economic impact on a substantial number of small entities since: (1) Leader company contracting is infrequently used by DoD; and (2) the primary factor in A–E selection is the determination of the most highly qualified firm; the SDB consideration is one of several secondary source selection factors. Therefore, an initial regulatory flexibility analysis has not been performed. Comments are invited from small businesses and other interested parties. Comments from small entities concerning the affected DFARS subparts also will be considered in accordance with 5 U.S.C. 610. Such comments should be submitted separately and should cite DFARS Case 98–D021 in correspondence.

C. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because the interim rule does not impose any information collection requirements that require the approval of the Office of Management and Budget under 44 U.S.C. 3501, *et seq.*

D. Determination To Issue an Interim Rule

A determination has been made under the authority of the Secretary of Defense that urgent and compelling reasons exist to publish an interim rule prior to affording the public an opportunity to comment. This interim rule amends the DFARS to conform it to the requirements of FAC 97–07, dated July 1, 1998, effective January 1, 1999. FAC 97–07 contains an interim rule amending the FAR to implement a DoJ proposal for reform of affirmative action in Federal procurement to ensure compliance with the constitutional standards established by the Supreme Court in *Adarand Constructors, Inc.* v. *Pena,* 115, S. Ct. 2097 (1995). The FAR rule contains an SDB participation program. Publication of an interim DFARS rule is necessary to conform the DFARS to the interim FAR rule effective January 1, 1999, and to the DoJ proposal implemented by the FAR rule. Comments received in response to the publication of this interim rule will be considered in formulating the final rule.

List of Subjects in 48 CFR Parts 215, 217, 219, 226, 236, and 252

Government procurement.

Michele P. Peterson,

Executive Editor, Defense Acquisition Regulations Council.

Therefore, 48 CFR Parts 215, 217, 219, 226, 236, 252, and Appendix I to Chapter 2 are amended as follows:

1. The authority citation for 48 CFR Parts 215, 217, 219, 226, 236, 252, and Appendix I to subchapter I continue to read as follows:

Authority: 41 U.S.C. 421 and 48 CFR Chapter 1.

PART 215—CONTRACTING BY NEGOTIATION

2. Section 215.304 is revised to read as follows:

215.304 Evaluation factors and significant subfactors.

(c)(i) In acquisitions that require use of the clause at FAR 52.219–9, Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan, other than those based on the lowest price technically acceptable source selection process (see FAR 15.101–2), the extent of participation of small businesses and historically black colleges or universities and minority institutions in performance of the contract shall be addressed in source selection. The contracting officer shall evaluate the extent to which offerors identify and commit to small business and historically black college or university and minority institution performance of the contract, whether as a joint venture, teaming arrangement, or subcontractor.

(A) Evaluation factors may include—

(1) The extent to which such firms are specifically identified in proposals;

(2) The extent of commitment to use such firms (for example, enforceable

commitments are to be weighted more heavily than non-enforceable ones);

(3) The complexity and variety of the work small firms are to perform;

(4) The realism of the proposal;

(5) Past performance of the offerors in complying with requirements of the clauses at FAR 52.219–8, Utilization of Small, Small Disadvantaged and Women-Owned Small Business Concerns, and 52.219–9, Small, Small Disadvantaged and Women-Owned Small Business Subcontracting Plan; and

(6) The extent of participation of such firms in terms of the value of the total acquisition.

(B) Proposals addressing the extent of small business and historically black college or university and minority institution performance may be separate from subcontracting plans submitted pursuant to the clause at FAR 52.219–9 and should be structured to allow for consideration of offers from small businesses.

(C) When an evaluation includes the factor in paragraph (c)(i)(B)*(1)* of this section, the small businesses, historically black colleges or universities and minority institutions, and women-owned small businesses considered in the evaluation shall be listed in any subcontracting plan submitted pursuant to FAR 52.219–9 to facilitate compliance with 252.219–7003(g).

(ii) The costs or savings related to contract administration and audit may be considered when the offeror's past performance or performance risk indicates the likelihood of significant costs or savings.

PART 217—SPECIAL CONTRACTING METHODS

3. Section 217.401 is revised to read as follows:

217.401 General.

(1) When leader company contracting is to be considered, take special effort to select a small disadvantaged business (SDB) concern as the follower company if—

(i) The follower company will be a subcontractor and the Standard Industrial Classification (SIC) Major Group of the acquisition is one in which use of an evaluation factor or subfactor for participation of SDB concerns is currently authorized (see FAR 19.201(b)); or

(ii) The follower company will be a prime contractor and the SIC Major Group of the acquisition is one in which use of a price evaluation adjustment is currently authorized (see FAR 19.201(b)).

(2) If special effort is required by paragraph (1) of this section and an SDB is not selected as the follower company, the contracting officer shall document the contract file to reflect—

(i) The extent of actions taken to identify SDB concerns for participation in the acquisition; and

(ii) The rationale for selection of a non-SDB as the follower company.

PART 219—SMALL BUSINESS PROGRAMS

4. Section 219.001 is revised to read as follows:

219.001 Definitions.

Small disadvantaged business concern is defined:

(1) At FAR 52.219–23(a) (i.e., a firm is considered a small disadvantaged business (SDB) concern by receiving certification by the Small Business Administration and meeting the other listed criteria), except as specified in paragraph (2) of this definition.

(2) At FAR 52.219–23(a) or 52.219–1(b)(2) for the following purposes (i.e., a firm is considered an SDB concern by either receiving certification by the Small Business Administration and meeting the other listed criteria or self-representing its status for general statistical purposes):

(i) A higher customary progress payment rate for SDB concerns (see 232.501–1(a)(i) and 252.232–7004(c)).

(ii) A lower threshold for inclusion of customary progress payments in contracts with SDB concerns (see 232.502–1).

(iii) The prompt payment policy for SDB concerns in 232. 903 and 232.905(2).

(iv) Reporting contract actions with SDB concerns (''Type of Business'' on the DD Form 350, Individual Contracting Action Report (see 253.204–70(d)(5)(i)(A)) or ''Small Disadvantaged Business (SDB) Actions'' on the DD Form 1057, Monthly Contracting Summary of Actions $25,000 or Less (see 253.204–71(g)(2)).

5. Section 219.708 is amended by revising paragraph (c)(1) and removing paragraph (c)(2). The revised text reads as follows:

219.708 Solicitation provisions and contract clauses.

* * * * * * *

(c)(1) Do not use the clause at FAR 52.219–10, Incentive Subcontracting Program, in contracts with contractors that have comprehensive subcontracting plans approved under the test program described in 219.702(a).

6. Subpart 219.12 is added to read as follows:

Subpart 219.12—Small Disadvantaged Business Participation Program

Sec.

219.1203 Incentive subcontracting with small disadvantaged business concerns.

The contracting officer shall encourage increased subcontracting opportunities for SDB concerns in negotiated acquisitions by providing monetary incentives in the SIC Major Groups for which use of an evaluation factor or subfactor for participation of SDB concerns is currently authorized (see FAR 19.201(b)). Incentives for exceeding SDB subcontracting targets shall be paid only if an SDB subcontracting target was exceeded as a result of actual subcontract awards to SDBs, and not a result of developmental assistance credit under the Pilot Mentor-Protégé Program (see Subpart 219.71).

219.1204 Solicitation provisions and contract clauses.

(c) The contracting officer shall, when contracting by negotiation, insert in solicitations and contracts containing the clause at FAR 52.219–25, Small Disadvantaged Business Participation Program-Disadvantaged Status and Reporting, a clause substantially the same as the clause at FAR 52.219–26, Small Disadvantaged Business Participation Program-Incentive Subcontracting, when authorized (see FAR 19.1203). The contracting officer may include an award fee provision in lieu of the incentive; in such cases, however, the contracting officer shall not use the clause at FAR 52.219–26. Do not use award fee provisions in contracts with contractors that have comprehensive subcontracting plans approved under the test program described in 219.702(a).

PART 226—OTHER SOCIOECONOMIC PROGRAMS

7. Section 226.7007 is amended by revising paragraph (b) to read as follows:

226.7007 Goals and incentives for subcontracting with HBCU/MIs.

* * * * *

(b) The contracting officer may, when contracting by negotiation, insert in solicitations and contracts a clause similar to the clause at FAR 52.219–10, Incentive Subcontracting Program, when a subcontracting plan is required, and inclusion of a monetary incentive is, in the judgment of the contracting officer, necessary to increase subcontracting opportunities for

historically black colleges or universities and minority institutions. The clause should include a separate goal for historically black colleges or universities and minority institutions.

PART 236—CONSTRUCTION AND ARCHITECT-ENGINEER CONTRACTS

8. Section 236.602–1 is amended by revising paragraph (a)(i)(6)(C) to read as follows:

236.602–1 Selection criteria.

(a) * * *

(i) * * *

(6) * * *

(C) Consider the extent to which potential contractors identify and commit to small business, to small disadvantaged business (SDB) if the Standard Industrial Classification Major Group of the subcontracted effort is one in which use of an evaluation factor or subfactor for participation of SDB concerns is currently authorized (see FAR 19.210(b)), and to historically black college or university and minority institution performance as subcontractors.

PART 252—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

252.212–7001 [Amended]

9. Section 252.212–7001 is amended by revising the clause date to read ''(JAN 1999)'', and by removing the entry at 252.219–7005.

252.219–7005 [Removed and Reserved]

10. Section 252.219–7005 is removed and reserved.

Appendix I to Chapter 2—[Amended]

11. Appendix I to Chapter 2 is amended by revising Section I–104 to read as follows:

Appendix I—Policy and Procedures for the DOD Pilot Mentor-Protégé Program

* * * * *

I–104 Eligibility requirements for a protégé firm.

(a) An entity may qualify as a protégé firm if it is—

(1) An SDB concern as defined at 219.001, paragraph (1) of the definition of ''small disadvantaged business concern,'' which is—

(i) Eligible for the award of Federal contracts; and

(ii) A small business according to the SBA size standard for the Standard Industrial Classification (SIC) code that represents the contemplated supplies or services to be provided by the protégé firm to the mentor firm; or

(2) A qualified organization employing the severely disabled as defined in Pub. L. 102–172, section 8064A.

(b) A protégé firm may self-certify to a mentor firm that it meets the eligibility requirements in paragraph (a) (1) or (2) of this section. Mentor firms may rely in good faith on a written representation that the entity meets the requirements of paragraph (a) (1) or (2) of this section, except for a protégé's status as a small disadvantaged business concern (see FAR 19.703(b)).

(c) A protégé firm may have only one active mentor-protégé agreement.

[FR Doc. 98–31039 Filed 11–19–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 980505118–8286–02; I.D. 110598B]

RIN 0648–AL14

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Shrimp Fishery of the Gulf of Mexico; Extension of Effective Date and Amendment of Bycatch Reduction Device Certification

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Interim rule; extension of expiration date; amendment; request for comments.

SUMMARY: An interim rule is in effect through November 16, 1998, that certifies the Jones-Davis and Gulf fisheye bycatch reduction devices (BRDs) for use in the Gulf of Mexico shrimp fishery. NMFS extends the interim rule through May 15, 1999, because conditions requiring the interim rule to reduce overfishing remain unchanged. NMFS also amends the interim rule regarding the specifications for the Jones-Davis, fisheye, and Gulf fisheye BRDs. The intended effects of this rule are to provide flexibility to Gulf shrimp trawlers for complying with the requirement to use a BRD and to maximize the effectiveness of BRDs. Providing a variety of certified BRDs will allow shrimpers to select a BRD based on how it matches the operating conditions their vessel encounters. This should enhance compliance, help minimize shrimp loss, and further increase bycatch reduction and, thus, further reduce overfishing of red snapper.

DATES: The expiration date for the interim rule published at 63 FR 27499, May 19, 1998, is extended to May 15, 1999. The amendment to Appendix D to part 622 that suspends paragraph E and adds paragraph F is effective November 17, 1998, through May 15, 1999. The amendment to Appendix D to part 622 that suspends paragraphs C.2. and D.2. and adds paragraphs C.3. and D.3. is effective November 27, 1998, through May 15, 1999.

ADDRESSES: Comments on this interim rule must be mailed to, and copies of documents supporting this rule may be obtained from, the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St Petersburg, FL 33702. Requests for copies of construction and installation instructions for the Jones-Davis, fisheye, and Gulf fisheye BRDs should be addressed to the Chief, Harvesting Systems Division, Mississippi Laboratories, Southeast Fisheries Science Center, NMFS, P.O. Drawer 1207, Pascagoula, MS 39568–1207.

FOR FURTHER INFORMATION CONTACT: Michael E. Justen, phone: 727–570–5305 or fax: 727–570–5583.

SUPPLEMENTARY INFORMATION: The Fishery Management Plan for the Shrimp Fishery of the Gulf of Mexico (FMP) was prepared by the Gulf of Mexico Fishery Management Council and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622.

Under section 305(c)(1) of the Magnuson-Stevens Act, NMFS published an interim rule (63 FR 27499, May 19, 1998) that certified the Jones-Davis and Gulf fisheye BRDs for use in the Gulf of Mexico shrimp fishery. Because conditions requiring the interim rule to reduce overfishing remain unchanged, NMFS extends the effective date of the interim rule through May 15, 1999, in accordance with section 305(c)(3)(B) of the Magnuson-Stevens Act.

In addition, NMFS amends Appendix D to Part 622—Specifications for Certified BRDs to revise the minimum construction and installation requirements for the Jones-Davis, fisheye, and Gulf fisheye BRDs. For the fisheye and Gulf fisheye BRDs, NMFS is prohibiting any part of the lazy line attachment system (i.e., any mechanism, such as elephant ears or choker straps, used to attach the lazy line to the codend) from overlapping, and thus obstructing, the fisheye escape opening. This will help to ensure effective bycatch reduction. For the Jones-Davis BRD, NMFS is adding alternative methods for constructing the 24–inch (61.0–cm) hoop and the funnel and

escape openings, thereby providing fishermen additional flexibility in complying with the BRD requirement.

Details concerning the basis for the certification of the Jones-Davis and Gulf fisheye BRDs are contained in the preamble to the initial interim rule and are not repeated here. No public comments on the initial interim rule were received. The fisheye BRD was certified in the final rule implementing Amendment 9 to the FMP (63 FR 18139, April 14, 1998).

Classification

The Assistant Administrator for Fisheries, NOAA (AA), has determined that this rule is necessary to enhance compliance with the BRD requirement for the Gulf shrimp fishery, improve effectiveness of bycatch reduction, and, thereby, reduce overfishing of red snapper in the Gulf of Mexico. The AA has also determined that this rule is consistent with the Magnuson-Stevens Act and other applicable laws.

This interim rule has been determined to be not significant for purposes of E.O. 12866.

Because prior notice and an opportunity for public comment are not required to be provided for this rule by 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq*., are inapplicable.

NMFS prepared a regulatory impact review (RIR) that provides an estimate of the costs and benefits of the interim rule. The RIR notes that the only identifiable costs associated with the rule are administrative costs of rule preparation; this cost was estimated at $5,000. This rule is expected to have positive effects on shrimp harvests and effort patterns because shrimpers will have the ability to choose among three BRD options instead of having to use the one BRD (i.e., fisheye) that was certified in Amendment 9 to the FMP. Positive effects will accrue because different shrimpers employ different harvesting tactics, pursue different shrimp species, operate in different geographical areas, and operate at varying times during the year. These differences in shrimp harvesting operations and conditions make it more efficient overall if a variety of BRDs are available. Over time, it is fully expected that a mix of available BRDs will be used to meet the BRD requirement. While the resulting benefits cannot be quantified, they may be fairly large. It is also expected that given the expanded choice of BRDs, compliance will be enhanced and the reduction in bycatch mortality will be increased relative to the status quo of a single BRD choice; therefore, there should be increased benefits to the red snapper fishery. Copies of the RIR are available (see **ADDRESSES**). NMFS has concluded that the restriction on placement of the lazy line attachment system will have negligible compliance costs but will help ensure effective bycatch reduction. The revisions to the specifications for the Jones-Davis BRD provide alternative construction methods that give fishermen greater flexibility in complying with the BRD requirement.

This rule extends the certification of the Jones-Davis and Gulf fisheye BRDs for use in the Gulf shrimp fishery, thereby providing shrimp trawlers flexibility in complying with the BRD requirement. This should enhance the compliance rate and reduce the bycatch mortality rate and, thus, reduce the overfishing of Gulf red snapper. The amendments to the BRD specifications are necessary to prevent impairment of the effectiveness of the fisheye and Gulf fisheye BRDs and to provide fishermen additional flexibility in complying with construction requirements for the Jones-Davis BRD. Accordingly, pursuant to authority set forth at 5 U.S.C. 553(b)(B), the AA finds that these reasons constitute good cause to waive the requirement to provide prior notice and the opportunity for prior public comment, as the delay associated with such procedures would be contrary to the public interest.

Similarly, under 5 U.S.C. 553(d)(3), the AA finds for good cause that a 30-day delay in the effective date of this rule, except for the amendments of the specifications for the fisheye and Gulf fisheye BRDs, would be contrary to the public interest. Because the amendments of the specifications for the fisheye and Gulf fisheye BRDs will require a minor gear adjustment for a small percentage of Gulf shrimp trawlers, NMFS delays the effective date of those provisions until November 27, 1998, to allow reasonable time for owners and operators to comply. The remaining aspects of the rule relieve restrictions by providing Gulf shrimp trawlers a choice of certified BRDs that may be used to comply with the BRD requirement that became effective on May 14, 1998, and by providing alternative construction methods for the Jones-Davis BRD. To the extent that this rule relieves restrictions by providing a choice of certified BRDs and additional flexibility in construction of the Jones-Davis BRD, it is not subject to a delay in effective date under 5 U.S.C. 553(d)(1).

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: November 16, 1998.

Andrew A. Rosenberg,

Deputy Assistant Administrator for Fisheries, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 622 is amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF, AND SOUTH ATLANTIC

1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq*.

2. Effective November 27, 1998, through May 15, 1999, in Appendix D to part 622, paragraphs C.2. and D.2. are suspended and paragraphs C.3. and D.3. are added to read as follows:

Appendix D to Part 622—Specifications for Certified BRDs

* * * * *

C. *Fisheye*.

* * * * *

3. *Minimum Construction and Installation Requirements*. The fisheye has a minimum opening dimension of 5 inches (12.7 cm) and a minimum total opening area of 36 square inches (91.4 square cm). The fisheye must be installed at the top center of the codend of the trawl to create an opening in the trawl facing in the direction of the mouth of the trawl no further forward than 11 ft (3.4 m) from the codend drawstring (tie-off rings) or 70 percent of the distance between the codend drawstring and the forward edge of the codend, excluding any extension, whichever is the shorter distance. In the Gulf EEZ only, when the fisheye BRD is installed in this position, no part of the lazy line attachment system (i.e., any mechanism , such as elephant ears or choker straps, used to attach the lazy line to the codend) may overlap the fisheye escape opening when the fisheye is installed aft of the attachment point of the codend retrieval system.

D. *Gulf fisheye*.

* * * * *

3. *Minimum Construction and Installation Requirements*. The Gulf fisheye is a cone-shaped rigid frame constructed of aluminum or steel rods. The rods must be at least 1/4–inch (6.35–mm) diameter. Any dimension of the escape opening must be at least 5.0 inches (12.7 cm), and the total escape opening area must be at least 36.0 in^2 (232.3 cm^2). The Gulf fisheye must be installed in the codend of the trawl to

create an escape opening in the trawl, facing in the direction of the mouth of the trawl, no further forward than 12.5 ft (3.81 m) and no less than 8.5 ft (2.59 m) from the codend tie-off rings. When installed in this position, no part of the lazy line attachment system (i.e., any mechanism, such as elephant ears or choker straps, used to attach the lazy line to the codend) may overlap the fisheye escape opening when the fisheye is installed aft of the attachment point of the codend retrieval system. The Gulf fisheye may not be offset more than 15 meshes perpendicular to the top center of the codend.

3. Effective November 17, 1998, through May 15, 1999, in Appendix D to part 622, paragraph E. is suspended and paragraph F. is added to read as follows:

Appendix D to Part 622—Specifications for Certified BRDs

* * * * *

F. *Jones-Davis*.

1. *Description*. The Jones-Davis BRD is similar to the expanded mesh and the extended funnel BRDs except that the fish escape openings are windows cut around the funnel rather than large-mesh sections. In addition, a webbing cone fish deflector is installed behind the funnel.

2. *Minimum Construction and Installation Requirements*. The Jones-Davis BRD must contain all of the following.

(a) *Webbing extension*. The webbing extension must be constructed from a single piece of 1 5/8–inch (3.5–cm) stretch mesh number 30 nylon 42 meshes by 120 meshes. A tube is formed from the extension webbing by sewing the 42–mesh side together.

(b) *28–inch (71.1–cm) cable hoop*. A single hoop must be constructed of ½-inch (1.3–cm) steel cable 88 inches (223.5 cm) in length. The cable must be joined at its ends by a 3–inch (7.6–cm) piece of ½-inch (1.3–cm) aluminum pipe and pressed with a 3/8–inch (0.95–cm) die to form a hoop. The inside diameter of this hoop must be between 27 and 29 inches (68.6 and 73.7 cm). The hoop must be attached to the extension webbing 17 ½ meshes behind the leading edge. The extension webbing must be quartered and attached in four places around the hoop, and every other mesh must be attached all the way around the hoop using number 24 twine or larger. The hoop must be laced with 3/8–inch (0.95–cm) polypropylene or polyethylene rope for chaffing.

(c) *24–inch (61.0–cm) hoop*. A single hoop must be constructed of either number 60 twine 80 inches (203.2 cm) in length or 3/8–inch (0.95–cm) steel cable 75 ½ inches (191.8 cm) in length. If twine is used, the twine must be laced in and out of the extension webbing 39 meshes behind the leading edge, and the ends must be tied together. If cable is used, the cable must be joined at its ends by a 3–inch (7.6–cm) piece of 3/8–inch (0.95–cm) aluminum pipe and pressed together with a 1/4–inch (0.64–cm) die to form a hoop. The inside diameter of this hoop must be between 23 and 25 inches (58.4 and 63.4 cm). The hoop must be attached to the extension webbing 39 meshes behind the leading edge. The extension webbing must be quartered and attached in four places around the hoop, and every other mesh must be attached all the way around the hoop using number 24 twine or larger. The hoop must be laced with 3/8–inch (0.95–cm) polypropylene or polyethylene rope for chaffing.

(d) *Funnel*. The funnel must be constructed from four sections of 1 ½-inch (3.8–cm) heat-set and depth-stretched polypropylene or polyethylene webbing. The two side sections must be rectangular in shape, 29 ½ meshes on the leading edge by 23 meshes deep. The top and bottom sections are 29 ½ meshes on the leading edge by 23 meshes deep and tapered 1 point 2 bars on both sides down to 8 meshes across the back. The four sections must be sewn together down the 23–mesh edge to form the funnel.

(e) *Attachment of the funnel in the webbing extension*. The funnel must be installed two meshes behind the leading edge of the extension starting at the center seam of the extension and the center mesh of the funnel's top section leading edge. On the same row of meshes, the funnel must be sewn evenly all the way around the inside of the extension. The funnel's top and bottom back edges must be attached one mesh behind the 28–inch (71.1–cm) cable hoop (front hoop). Starting at the top center seam, the back edge of the top funnel section must be attached four meshes each side of the center. Counting around 60 meshes from the top center, the back edge of the bottom section must be attached 4 meshes on each side of the bottom center. Clearance between the side of the funnel and the 28–inch (71.1–cm) cable hoop (front hoop) must be at least 6 inches (15.2 cm) when measured in the hanging position.

(f) *Cutting the escape openings*. The leading edge of the escape opening must be located within 18 inches (45.7 cm) of the posterior edge of the turtle excluder device (TED) grid. The area of the escape opening must total at least 864 in^2 (5,574.2 cm^2). Two escape openings 10 meshes wide by 13 meshes deep must be cut 6 meshes apart in the extension webbing, starting at the top center extension seam, 3 meshes back from the leading edge and 16 meshes to the left and to the right (total of four openings). The four escape openings must be double selvaged for strength.

(g) *Alternative Method for Constructing the Funnel and Escape Openings*. The following method for constructing the funnel and escape openings may be used instead of the method described in paragraphs F.2.d., F.2.e., and F.2.f. of this section. With this alternative method, the funnel and escape openings are formed by cutting a flap in each side of the extension webbing; pushing the flaps inward; and attaching the top and bottom edges along the bars of the extension webbing to form the v-shape of the funnel. Minimum requirements applicable to this method include: (1) The funnel's top and bottom back edges must be attached one mesh behind the 28–inch (71.1–cm) cable hoop (front hoop). (2) Clearance between the side of the funnel and the 28–inch (71.1–cm) cable hoop (front hoop) must be at least 6 inches (15.2 cm) when measured in the hanging position. (3) The leading edge of the escape opening must be located within 18 inches (45.7 cm) of the posterior edge of the turtle excluder device (TED) grid. (4) The area of the escape opening must total at least 864 in^2 (5,574.2 cm^2). To construct the funnel and escape openings using this method, begin 3 ½ meshes from the leading edge of the extension, at the top center seam, count over 18 meshes on each side, and cut 13 meshes toward the back of the extension. Turn parallel to the leading edge, and cut 26 meshes toward the bottom center of the extension. Next, turn parallel to the top center seam, and cut 13 meshes forward toward the leading edge, creating a flap of webbing 13 meshes by 26 meshes by 13 meshes. Lengthen the flap to 18 meshes by adding a 4 ½-mesh by 26–mesh rectangular section of webbing to the 26–mesh edge. Attach the 18–mesh edges to the top and bottom of the extension by sewing 2 bars of the extension to 1 mesh on the flap in toward the top center and bottom center of the extension, forming the exit opening and the funnel. Connect the two flaps together in the center with a 7–inch piece of number 42 twine to allow adequate clearance for fish escapement between the flaps and the side openings. On each side, sew a 6–mesh by 10 ½-mesh section of webbing to 6 meshes of the center of the 26–mesh

cut on the extension and 6 meshes centered between the 13–mesh cuts 3 ½ meshes from the leading edge. This forms two 10–mesh by 13–mesh openings on each side.

(h) *Cone fish deflector.* The cone fish deflector is constructed of 2 pieces of 1 5/8–inch (4.13–cm) polypropylene or polyethylene webbing, 40 meshes wide by 20 meshes in length and cut on the bar on each side forming a triangle. Starting at the apex of the two triangles, the two pieces must be sewn together to form a cone of webbing. The apex of the cone fish deflector must be positioned within 10–14 inches (25.4–35.6 cm) of the posterior edge of the funnel.

(i) *11–inch (27.9–cm) cable hoop for cone deflector.* A single hoop must be constructed of 5/16–inch (0.79–cm) or 3/8–inch (0.95–cm) cable 34 ½ inches (87.6 cm) in length. The ends must be joined by a 3–inch (7.6–cm) piece of 3/8–inch (0.95–cm) aluminum pipe pressed together with a 1/4–inch (0.64–cm) die. The hoop must be inserted in the webbing cone, attached 10 meshes from the apex and laced all the way around with heavy twine.

(j) *Installation of the cone in the extension.* The cone must be installed in the extension 12 inches (30.5 cm) behind the back edge of the funnel and attached in four places. The midpoint of a piece of number 60 twine 4 ft (1.22 m) in length must be attached to the apex of the cone. This piece of twine must be attached to the 28–inch (71.1–cm) cable hoop at the center of each of its sides; the points of attachment for the two pieces of twine must be measured 20 inches (50.8 cm) from the midpoint attachment. Two 8–inch (20.3–cm) pieces of number 60 twine must be attached to the top and bottom of the 11–inch (27.9–cm) cone hoop. The opposite ends of these two pieces of twine must be attached to the top and bottom center of the 24–inch (61–cm) cable hoop; the points of attachment for the two pieces of twine must be measured 4 inches (10.2 cm) from the points where they are tied to the 11–inch (27.9–cm) cone hoop.

[FR Doc. 98–30993 Filed 11–6–8; 5:04 pm]

BILLING CODE 3510–22–F

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 971015246–7293–02; I.D. 111698E]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Commercial Quota Harvested for New Jersey

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Commercial quota harvest.

SUMMARY: NMFS announces that the summer flounder commercial quota available to the State of New Jersey has been harvested. Vessels issued a commercial Federal fisheries permit for the summer flounder fishery may not land summer flounder in New Jersey for the remainder of calendar year 1998 unless additional quota becomes available through a transfer. Regulations governing the summer flounder fishery require publication of this notification to advise the State of New Jersey that the quota has been harvested and to advise vessel permit holders and dealer permit holders that no commercial quota is available for landing summer flounder in New Jersey.

DATES: Effective 0001 hours November 21, 1998, through December 31, 1998.

FOR FURTHER INFORMATION CONTACT: Paul H. Jones, Fishery Policy Analyst, (978) 281–9273.

SUPPLEMENTARY INFORMATION:

Regulations governing the summer flounder fishery are found at 50 CFR part 648. The regulations require annual specification of a commercial quota that is apportioned among the coastal states from North Carolina through Maine. The process to set the annual commercial quota and the percent allocated to each state are described in § 648.100.

The initial total commercial quota for summer flounder for the 1998 calendar year was set equal to 11,105,636 lb (5,037,432 kg) (62 FR 66304, December 18, 1997). The percent allocated to vessels landing summer flounder in New Jersey is 16.72499 percent, or 1,858,363 lb (842,954 kg).

Section 648.101(b) requires the Administrator, Northeast Region, NMFS (Regional Administrator), to monitor state commercial quotas and to determine when a state's commercial quota is harvested. The Regional Administrator is further required to publish notification in the **Federal Register** advising a state and notifying Federal vessel and dealer permit holders that, effective upon a specific date, the state's commercial quota has been harvested and no commercial quota is available for landing summer flounder in that state. The Regional Administrator has determined, based upon dealer reports and other available information, that the State of New Jersey has attained its quota for 1998.

The regulations at § 648.4(b) provide that, as a condition of the permit, Federal permit holders agree not to land summer flounder in any state that the Regional Administrator has determined no longer has commercial quota available. Therefore, effective 0001 hours November 21, 1998, further landings of summer flounder in New Jersey by vessels holding commercial Federal fisheries permits are prohibited for the remainder of the 1998 calendar year unless additional quota becomes available through a transfer and is announced in the **Federal Register**. Effective November 21, 1998, federally permitted dealers are also advised that they may not purchase summer flounder from federally permitted vessels that land in New Jersey for the remainder of the calendar year, or until additional quota becomes available through a transfer.

Classification

This action is required by 50 CFR part 648 and is exempt from review under E.O. 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 17, 1998.

Richard W. Surdi,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–31097 Filed 11–19–98; 8:45 am]

BILLING CODE 3510–22–F

Proposed Rules

Federal Register
Vol. 63, No. 224
Friday, November 20, 1998

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 70

Public Meeting on Part 70 Rulemaking Activities

AGENCY: Nuclear Regulatory Commission (NRC).

ACTION: Notice of meeting.

SUMMARY: NRC will host a public meeting in Rockville, Maryland with representatives of the Nuclear Energy Institute (NEI) to discuss the NRC staff's proposed revisions to 10 CFR part 70, ''Domestic Licensing of Special Nuclear Material.''

NRC staff and NEI representatives briefed the Commission on August 25, 1998, regarding SECY–98–185, ''Proposed Rulemaking—Revised Requirements for the Domestic Licensing of Special Nuclear Material,'' dated July 30, 1998. Although both NRC staff and NEI are in agreement that part 70 should be amended to require the performance of an integrated safety analysis (ISA), disagreements about the details of that proposed requirement were identified at the Commission meeting. At a subsequent public meeting on September 29, 1998, NRC staff and industry representatives discussed some of the issues, but agreed that an additional meeting was needed.

DATES: The meeting is scheduled for December 3–4, 1998, from 9 a.m. to 4 p.m. The meeting is open to the public. Persons with administrative questions concerning this meeting should contact James Hennigan at (301) 415–6850.

ADDRESSES: NRC's Auditorium at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland. Visitor parking around the NRC building is limited; however, the meeting site is located adjacent to the White Flint Station on the Metro Red Line.

FOR FURTHER INFORMATION CONTACT: Theodore S. Sherr, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, telephone: (301) 415–7218, e-mail: *tss@nrc.gov*.

SUPPLEMENTARY INFORMATION:

Purpose: The purpose of this meeting is for NRC to consider industry's suggestions for specific changes to the language in the SECY–98–185 draft amendment to 10 CFR part 70, and the associated draft standard review plan (SRP). Topics to be addressed are: (1) Next steps in the revision of 10 CFR part 70; (2) chemical safety requirements; (3) SRP issues; (4) criticality safety in relation to risk-informed regulations; (5) the content of the ISA summary; (6) the role of the preliminary ISA in the regulatory process; and (7) other issues identified.

Additional information is available on the NRC technical conferences website through the NRC home page (*http://www.nrc.gov*). This information includes: (1) The NRC staff recommendations sent to the Commission for consideration (SECY–98–185); (2) a transcript of the August 25, 1998, briefing to the Commission; and, (3) a transcript of a September 29, 1998, public meeting between NRC staff and NEI. On the NRC home page select ''Rulemaking'' from the tool bar. The Technical Conference Forum home page can then be accessed by selecting ''Technical Conferences''. Again select ''Technical Conferences,'' and then ''Revised Requirements for the Domestic Licensing of Special Nuclear Material (Part 70).'' Alternatively, you may direct your browser to go directly to *http://techconf.LLNL.gov/cgi-bin/topics*. For information about the technical conferences website, contact Ms. Carol Gallagher, (301) 415–8149; e-mail cag@nrc.gov.

Dated at Rockville, Maryland this 16th day of November, 1998.

For the Nuclear Regulatory Commission.

Elizabeth Q. Ten Eyck,

Director, Division of Fuel Cycle Safety and Safeguards.

[FR Doc. 98–31024 Filed 11–19–98; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 658

[FHWA Docket No. FHWA–98–4326]

RIN 2125–AE43

Truck Size and Weight; Definitions; Nondivisible

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); request for comments.

SUMMARY: The FHWA proposes to modify its definition of nondivisible load or vehicle to include marked military vehicles. This will allow, but not require, States to issue overweight permits for such vehicles to operate on the Interstate System.

DATES: Comments on this docket must be received on or before January 19, 1999.

ADDRESSES: Signed, written comments should refer to the docket number that appears at the top of this document and must be submitted to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW, Washington, DC 20590–0001. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays. Those desiring notification of receipt of comments must include a self-addressed, stamped envelope or postcard.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Klimek, Office of Motor Carrier Information Management and Analysis (202) 366–2212, or Mr. Charles Medalen, Office of the Chief Counsel (202) 366–1354, Federal Highway Administration, 400 Seventh Street, SW., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except legal Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

Internet users can access all comments received by the U.S. Dockets, Room PL–401, by using the universal resource locator (URL): http://dms.dot.gov. It is available 24 hours each day, 365 days each year. Please follow the instructions online for more information and help.

An electronic copy of this document may be downloaded using a modem and suitable communications software from the Government Printing Office's Electronic Bulletin Board Service at (202) 512–1661. Internet users may reach the Federal Register's home page at: http://www.nara.gov/fedreg and the Government Printing Office's database at: http://www.access.gpo.gov/nara.

Background

States must adopt and enforce Federal weight standards for the Interstate System or risk the loss of certain Federal-aid highway funds. These standards are 20,000 pounds on a single axle, 34,000 pounds on a tandem axle, and the weights specified by the bridge formula, up to a maximum gross vehicle weight of 80,000 pounds. The bridge formula is designed to ensure that a vehicle is sufficiently long and has enough axles to protect bridges by spreading the weight over a large area of bridge decking and supports. Some States also have grandfathered weight limits which exceed Interstate System standards, usually because they were in effect in a State before the Interstate limits were adopted. In addition, all States may issue permits allowing nondivisible loads or vehicles, i.e., those that cannot be easily dismantled or divided, to use Interstate highways at weights above the normal Interstate limits. The FHWA has defined nondivisible load or vehicle in 23 CFR 658.5 as follows:

(1) As used in this part, *nondivisible* means any load or vehicle exceeding applicable length or weight limits which, if separated into smaller loads or vehicles, would:

(i) Compromise the intended use of the vehicle, i.e., make it unable to perform the function for which it was intended;

(ii) Destroy the value of the load or vehicle, i.e., make it unusable for its intended purpose; or

(iii) Require more than 8 workhours to dismantle using appropriate equipment. The applicant for a nondivisible load permit has the burden of proof as to the number of workhours required to dismantle the load.

(2) A State may treat emergency response vehicles and casks designed for the transport of spent nuclear materials as nondivisible vehicles or loads.

The Department of Defense's Military Traffic Management Command (MTMC) petitioned the FHWA for rulemaking to amend this definition to include marked military vehicles. The MTMC pointed out that since the end of the Cold War, the number of military units deployed overseas has declined, with the result that the bulk of our military forces are based in the continental United States. Current mobility strategy requires the capability to deploy military forces from the United States to any point where they may be needed. The nation's highways, particularly the Interstate System, play a significant role in such actions. Training exercises are essential to the performance of this mission since troops in actual deployments must be familiar with highway operations in order to assure safe and efficient transportation. The FHWA granted the MTMC petition for rulemaking on May 20, 1998. This notice sets forth the substance of the MTMC petition, proposes changes to the regulations at 23 CFR part 658 to accommodate MTMC's position, and solicits comments on the proposed revision of the nondivisible load or vehicle definition in the involved regulations.

Under the current FHWA definition, some overweight military vehicles, such as the M–1 Abrams main battle tank, readily qualify as nondivisible. Other vehicles and equipment, however, would be classified as divisible. If a State does not issue overweight permits for divisible loads—a practice governed by complicated ''grandfather rights'' which vary from State to State—these military cargoes must be disassembled into their constituent parts before they can be transported on the Interstate System. This requirement impedes military exercises intended to maintain or improve operational readiness.

One of the vehicles particularly affected by the current definition of nondivisibility is the Army's palletized load system (PLS). The PLS is a very large, rugged vehicle designed to operate off-road delivering munitions and other mission-critical supplies to front-line troops. The PLS is a 5-axle straight truck and 3-axle full trailer with an overall length of just under 60 feet, a wheelbase of just under 50 feet, and a maximum gross weight of 132,840 pounds. It weighs almost 66,500 pounds empty. If the straight truck is equipped with a material handling crane, the gross weight rises to 137,520 pounds and the empty weight to about 71,500 pounds. The loaded weights exceed the normal 80,000 pound Interstate weight limit, as well as the bridge formula limit for an 8-axle vehicle with a wheelbase of 50 feet (94,500 pounds). While the Army can operate these vehicles off-road at any time, PLS crews also need the opportunity to train for rapid deployment from bases in the United States to airfields or ports of embarkation. Such exercises often involve the use of Interstate highways.

An argument could be made that the PLS meets the current definition of a nondivisible load or vehicle because reducing its weight to normal Interstate limits would compromise its intended use or make it unusable for its intended purpose. Similar arguments, however, can be made for any commercial vehicle with a maximum designed gross weight in excess of the Federal limits. As the FHWA said in its February 25, 1993, preamble to a Supplemental Notice of Proposed Rulemaking (SNPRM), which included a proposed definition of a nondivisible load or vehicle,

> The intended use of a vehicle is not ''compromised'' simply because it is required to comply with applicable weight limits. For example, the fact that a combination with a GCWR (gross combination weight rating) of 90,000 or 100,000 pounds may not be allowed to operate on the Interstate at more than 80,000 pounds does not compromise its intended use since the vehicle's cargo-carrying function remains entirely unchanged. This (proposed) definition does not imply that vehicles must be allowed to operate at their design limits.
>
> (58 FR 11450, at 11456, February 25, 1993.)

If the existing definition of a nondivisible load or vehicle were interpreted as including the PLS or other large military vehicles, the same rationale could force the FHWA to treat commercial vehicles designed to carry heavy loads as nondivisible. The result would be the replacement of Federal weight limits with State permit limits.

Nevertheless, a regulation which makes it difficult for the States to allow the operation of large military vehicles on the Interstate System is indefensible. Amending the definition in 23 CFR. 658.5 will enable the States to make nondivisible load permits available to military equipment without risking the loss of Federal-aid highway funds. This will not compromise the ability of the FHWA to maintain reasonable limits on the use of such permits by commercial motor vehicles and carriers. Commercial trucking is essential to the U.S. economy, but military vehicles are designed and operated differently and serve fundamentally different purposes. This rulemaking does not establish a precedent applicable to civilian vehicles.

The FHWA proposes to amend paragraph (2) of the definition of a ''nondivisible load or vehicle'' by adding ''marked military equipment or materiel'' to the vehicles and equipment already listed there. This will enable, but not require, States to issue nondivisible load permits to vehicles qualifying as, or transporting, marked military equipment or materiel. The term ''marked military equipment or

materiel'' has two components: (1) There must be some kind of marking which openly identifies the equipment or materiel as belonging to U.S. military forces. This could take the form of individual service markings (''U.S. Army''), Federal license plates or even color (e.g., desert camouflage paint), and (2) the vehicle or load must be directly related to the military's combat or defense mission. In addition to more obvious items such as tanks or cannon, crates of ammunition, field medical supplies, or any other consumable that is directly used by troops would be covered by this definition. Conversely, crates of household furnishings owned by military personnel, or commercial concrete mixer trucks delivering to a construction site on a military base would not qualify under this definition.

We believe it is appropriate to allow States to issue nondivisible-load permits authorizing overweight movements of marked military equipment or materiel on the Interstate System. This is not to say that States should issue permits without consideration of the structural limits of their pavements or bridges. But withholding the discretion to accommodate the needs of U.S. military forces would be a disservice to the nation.

Rulemaking Analyses and Notices

All comments received before the close of business on the comment closing date indicated above will be considered and will be available for examination using the docket number appearing at the top of this document in the docket room at the above address. The FHWA will file comments received after the comment closing date in the docket and will consider late comments to the extent practicable. The FHWA may, however, issue a final rule at any time after the close of the comment period. In addition to late comments, the FHWA will also continue to file, in the docket, relevant information becoming available after the comment closing date, and interested persons should continue to examine the docket for new material.

Executive Order 12866 (Regulatory Planning and Review) and DOT Regulatory Policies and Procedures

The FHWA has determined that this action does not constitute a significant regulatory action within the meaning of E.O. 12866, nor is it considered significant under the regulatory policies and procedures of the DOT. It is anticipated that the economic impact of this rulemaking will be minimal. This rulemaking proposes to allow States to issue overweight permits for marked military vehicles to travel on the Interstate System. The effect on that System will be negligible and under full control by the States. Therefore, a full regulatory evaluation is not required.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (5 U.S.C. 601–612), the FHWA has evaluated the effects of this proposal on small entities. This rulemaking affects only States and the Department of Defense.

Based on its evaluation of this proposal, the FHWA certifies that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12612 (Federalism Assessment)

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the proposed rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Executive Order 12372 (Intergovernmental Review)

Catalog of Federal Domestic Assistance Program Number 20.217, Motor Carrier Safety. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal Programs and activities do not apply to this program.

Paperwork Reduction Act

The proposal in this document does not contain information collection requirements for the Paperwork Reduction Act of 1995, 44 U.S.C. 3501–3520.

National Environmental Policy Act

The agency has analyzed this action for the purpose of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and has determined that this action would not have any effect on the quality of the environment.

Unfunded Mandates Reform Act

This proposed rule would not impose a Federal mandate resulting in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year (2 U.S.C. 1532).

Regulation Identification Number

A regulation identification Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document can be used to cross reference this action with the Unified Agenda.

List of Subjects in 23 CFR Part 658

Grants programs—transportation, Highway and roads, Motor carrier—size and weight.

Issued on: November 13, 1998.

Kenneth R. Wykle,

Federal Highway Administrator.

In consideration of the foregoing, the FHWA proposes to amend title 23, Code of Federal Regulations, part 658, as set forth below:

PART 658—TRUCK SIZE AND WEIGHT, ROUTE DESIGNATIONS—LENGTH, WIDTH AND WEIGHT LIMITATIONS

1. The authority citation for 23 CFR Part 658 is revised to read as follows:

Authority: 23 U.S.C. 127 and 315; 49 U.S.C. 31111—31114 ; 49 CFR 1.48.

2. The definition of ''nondivisible load or vehicle'' in 23 CFR 658.5 is amended to read as follows:

§ 658.5 Definitions.

* * * * *

Nondivisible load or vehicle.

(1) As used in this part, *nondivisible* means any load or vehicle exceeding applicable length or weight limits which, if separated into smaller loads or vehicles, would:

(i) Compromise the intended use of the vehicle, i.e., make it unable to perform the function for which it was intended;

(ii) Destroy the value of the load or vehicle, i.e., make it unusable for its intended purpose; or

(iii) Require more than 8 workhours to dismantle using appropriate equipment. The applicant for a nondivisible load permit has the burden of proof as to the number of workhours required to dismantle the load.

(2) A State may treat emergency response vehicles, casks designed for the transport of spent nuclear materials, and marked military equipment or materiel as nondivisible vehicles or loads.

* * * * *

[FR Doc. 98–31034 Filed 11–19–98; 8:45 am]

BILLING CODE 4910–22–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 81

[AZ–001–BU FRL–6183–8]

Clean Air Act Reclassification; Arizona-Phoenix Nonattainment Area; Ozone; Extension of Plan Submittal Deadline

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: On November 6, 1997, EPA published a rule announcing our finding that the Phoenix, Arizona, metropolitan area had failed to attain the 1-hour national ambient air quality standard for ozone as required by the Federal Clean Air Act (CAA or the Act). This finding resulted in the area being reclassified by operation of law from a ''moderate'' to a ''serious'' ozone nonattainment area. In the rule, we also set a deadline of December 8, 1998 for Arizona to submit the revisions to its implementation plan that are needed to meet the Act's requirements for serious ozone nonattainment areas. Here, we are proposing a short extension of that deadline to March 22, 1999.

DATES: Comments may be submitted in writing until December 7, 1998.

ADDRESSES: Please address any comments you may have on this document to Frances Wicher at the address listed below. We have placed information related to this proposed action into a docket. You may look at the docket during normal business hours at the U.S. Environmental Protection Agency, Region 9, Office of Air Planning, 17th floor, 75 Hawthorne Street, San Francisco, California 94105.

We have also placed a copy of this document in the air programs section of our website at www.epa.gov/region09/air.

FOR FURTHER INFORMATION CONTACT: Frances Wicher, Office of Air Planning (AIR–2), U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, California 94105. (415) 744–1248 or wicher.frances@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Background

What is Being Proposed in This Action?

EPA is proposing to extend by three and one-half months, until March 22, 1999, the date by which the State of Arizona must submit the revisions to the Phoenix metropolitan area's state implementation plan (SIP) that are needed to meet the Clean Air Act's requirements for serious ozone nonattainment areas. The current submittal date is December 8, 1998.

We have discussed the reasons for this submittal date extension in a direct final rule which you can find in the Rules Section of this **Federal Register**.

We are extending the submittal deadline for the Phoenix-area serious ozone plan in a direct final rule without first proposing the rule and providing an opportunity for public comment. We are finalizing this rule directly because we believe this is noncontroversial and do not expect to receive unfavorable comments on it. If we do not receive unfavorable comments, we will take no further action on this proposed rule. If we do receive unfavorable comments, then we will withdraw the final rule and inform the public that the rule will not take effect. We will then address all public comments in a later final rule. Since there will not be a second comment period on this action, any member of the public who wants to comment on it should do so at this time.

Authority: 42 U.S.C. 7401 *et seq.*

Date Signed: October 24, 1998.

Felicia Marcus,

Regional Administrator, Region IX.

[FR Doc. 98–29821 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 82

[FRL–6191–5]

Protection of Stratospheric Ozone: Allocation of 1999 Essential-Use Allowances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking.

SUMMARY: With this action, EPA is proposing the allocation of essential-use allowances for the 1999 control period. The United States nominated specific uses of controlled ozone-depleting substances (ODS) as essential for 1999 under the Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol). The Parties to the Protocol subsequently authorized specific quantities of ODS for 1999 for the uses nominated by the United States. Essential-use allowances permit a person to obtain controlled ozone-depleting substances as an exemption to the January 1, 1996 regulatory phaseout of production and import. Essential-use allowances are allocated to a person for exempted production or importation of a specific quantity of a controlled substance solely for the designated essential purpose.

DATES: Written comments on this proposed rule must be received on or before December 21, 1998, unless a public hearing is requested. Comments must then be received on or before 30 days following the public hearing. Any party requesting a public hearing must notify the Stratospheric Ozone Protection Hotline listed below by 5 p.m. Eastern Standard Time on November 30, 1998. If a hearing is held, EPA will publish a document in the **Federal Register** announcing the hearing information.

ADDRESSES: Comments on this rulemaking should be submitted in duplicate (two copies) to: Air Docket No. A–92–13, U.S. Environmental Protection Agency, 401 M Street, SW, Room M–1500, Washington, DC, 20460. Inquiries regarding a public hearing should be directed to the Stratospheric Ozone Protection Hotline at 1–800–269–1996.

Materials relevant to this rulemaking are contained in Docket No. A–92–13. The Docket is located in room M–1500, First Floor, Waterside Mall at the address above. The materials may be inspected from 8 a.m. until 4 p.m. Monday through Friday. A reasonable fee may be charged by EPA for copying docket materials.

FOR FURTHER INFORMATION CONTACT: The Stratospheric Ozone Protection Hotline at 1–800–296–1996 or Tom Land, U.S. Environmental Protection Agency, Stratospheric Protection Division, Office of Atmospheric Programs, 6205J, 401 M Street, SW., Washington, DC, 20460, 202–564–9185.

SUPPLEMENTARY INFORMATION:

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I. Background

The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol)

sets specific deadlines for the phaseout of production and importation of ozone depleting substances (ODS). At their Fourth Meeting in 1992, the signatories to the Protocol (the Parties) amended the Protocol to allow exemptions to the phaseout for uses agreed by the Parties to be essential. At the same Meeting, the Parties also adopted Decision IV/25, which established both criteria for determining whether a specific use should be approved as essential and a process for the Parties to use in making such a determination.

The criteria for an essential use as set forth in Decision IV/25 are the following: ''(1) That a use of a controlled substance should qualify as 'essential' only if:

(i) It is necessary for the health, safety or is critical for the functioning of society (encompassing cultural and intellectual aspects); and

(ii) There are no available technically and economically feasible alternatives or substitutes that are acceptable from the standpoint of environment and health;

(2) That production and consumption, if any, of a controlled substance for essential uses should be permitted only if:

(i) All economically feasible steps have been taken to minimize the essential-use and any associated emission of the controlled substance; and

(ii) The controlled substance is not available in sufficient quantity and quality from existing stocks of banked or recycled controlled substances, also bearing in mind the developing countries' need for controlled substances.''

Decision IV/25 also sets out the procedural steps for implementing this process. It first calls for individual Parties to nominate essential-uses. These nominations are then to be evaluated by the Protocol's Technology and Economic Assessment Panel (TEAP or the Panel) which makes recommendations to representatives of all Protocol Parties. The final decision on which nominations to approve is to be taken by a meeting of the Parties.

II. Allocation of 1999 Essential-Use Allowances

In today's action, EPA is proposing allocation of essential-use allowances for the 1999 control period to entities listed in Table I for exempted production or import of the specific quantity of class I controlled substances solely for the specified essential-use.

TABLE I.—ESSENTIAL USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 1999 AND ESSENTIAL-USE ALLOWANCES

Company/Entity	Class I controlled substance	Quantity (metric tonnes)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
International Pharmaceutical Aerosol Consortium (IPAC)—Armstrong Laboratories, Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, Schering-Plough Corporation, 3M.	CFC–11	899.5
	CFC–12	2157.4
	CFC–114	183.6
Medisol Laboratories, Inc.	CFC–11	67.3
	CFC–12	115.3
	CFC–114	9.6
Aeropharm Technology, Inc.	CFC–11	80.1
	CFC–12	160.2
Sciarra Laboratories, Inc.	CFC–11	0.5
	CFC–12	1.5
	CFC–114	0.5
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4
(iii) Laboratory and Analytical Applications		
Global Exemption (Restrictions in Appendix G Apply)	All Class I Controlled Substances (except Group VI).	No quantity specified

The International Pharmaceutical Aerosol Consortium (IPAC) consolidated requests for an essential-use exemption to be nominated to the Protocol as an agent of its member companies for administrative convenience. By means of a confidential letter to each of the companies listed above, EPA will allocate essential-use allowances separately to each company in the amount requested by it for the nomination.

Applications submitted by the entities in Table I requested class I controlled substances for uses claimed to be essential during the 1999 control period. The applications provided information in accordance with the criteria set forth in Decision IV/25 of the Protocol and the procedures outlined in the ''Handbook on Essential-Use Nominations.'' The applications request exemptions for the production and import of specific quantities of specific class I controlled substances after the phaseout as set forth in 40 CFR 82.4. The applications were reviewed by the U.S. government and nominated to the Protocol Secretariat for analysis by the Technical and Economic Assessment Panel (TEAP) and its Technical Option Committees (TOCs). The Parties to the Montreal Protocol approved the U.S. nominations for essential-use exemptions during the Ninth Meeting in 1997 (Decision IX/18). Today's action proposes the allocation of essential-use allowances to United States entities based on nominations decided upon by the Parties to the Protocol.

The 1999 global essential-use exemption for analytical and laboratory applications published in today's proposed rule does not alter the strict requirements both in 40 CFR 82.13 and in Appendix G to 40 CFR part 82, subpart A. The restrictions for the global laboratory and analytical essential-use exemption listed in Appendix G include requirements regarding purity of the class I controlled substances and the size of the containers. In addition, there are detailed reporting requirements in § 82.13 for persons that take advantage of the global laboratory and analytical essential-use exemption for class I controlled substances. The strict requirements are established because the Parties to the Protocol, and today's proposed rule, do not specify a quantity of essential-use allowances permitted for analytical and laboratory applications, but establish a global essential-use exemption, without a named recipient.

Any person obtaining class I controlled substances after the phaseout under the essential-use exemptions proposed in today's action would be subject to all the restrictions and requirements in other sections of 40 CFR part 82, subpart A. Holders of essential-use allowances or persons obtaining class I controlled substances under the essential-use exemptions must comply with the record keeping and reporting requirements in § 82.13 and the restrictions in Appendix G.

III. Summary of Supporting Analysis

A. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector.

Under section 202 of the UMRA, EPA generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year. Before promulgating an EPA rule for which a written statement is needed, section 205 of the UMRA generally requires EPA to identify and consider a reasonable number of regulatory alternatives and adopt the least costly, most cost-effective or least burdensome alternative that achieves the objectives of the rule. The provisions of section 205 do not apply when they are inconsistent with applicable law. Moreover, section 205 allows EPA to adopt an alternative other than the least costly, most cost-effective or least burdensome alternative if the Administrator publishes with the final rule an explanation why that alternative was not adopted. Section 204 of the UMRA requires the Agency to develop a process to allow elected state, local, and tribal government officials to provide input in the development of any proposal containing a significant Federal intergovernmental mandate.

Before EPA establishes any regulatory requirements that may significantly or uniquely affect small governments, including tribal governments, it must have developed under section 203 of the UMRA a small government agency plan. The plan must provide for notifying potentially affected small governments, enabling officials of affected small governments to have meaningful and timely input in the development of EPA regulatory proposals with significant Federal intergovernmental mandates, and informing, educating, and advising small governments on compliance with the regulatory requirements.

Today's rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local, or tribal governments or the private sector. Because this proposed rule imposes no enforceable duty on any State, local or tribal government it is not subject to the requirements of sections 202 and 205 of the UMRA. EPA has also determined that this rule contains no regulatory requirements that might significantly or uniquely affect small governments; therefore, EPA is not required to develop a plan with regard to small governments under section 203. Finally, because this proposal does not contain a significant intergovernmental mandate, the Agency is not required to develop a process to obtain input from elected state, local, and tribal officials under section 204.

B. Executive Order 12875: Enhancing the Intergovernmental Partnership

Under Executive Order 12875, EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments or EPA consults with those governments. If EPA complies by consulting, Executive Order 12875 requires EPA to provide the Office of Management and Budget a description of the extent of EPA's prior consultation with representatives of affected State, local and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's proposed rule does not create a mandate on State, local or tribal governments. The proposed rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this proposed rule.

C. Executive Order 12866

Under Executive Order 12866 (58 FR 51735, October 4, 1993), the Agency must determine whether this regulatory action is ''significant'' and therefore subject to OMB review and the requirements of the Executive Order. The Order defines ''significant'' regulatory action as one that is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

It has been determined that this rule is not a ''significant regulatory action'' under the terms of Executive Order 12866 and is therefore not subject to OMB review.

D. Paperwork Reduction Act

This action does not add any information collection requirements or increase burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 et seq. The Office of Management and Budget (OMB) previously approved the information collection requirements contained in the final rule promulgated on May 10, 1995, and assigned OMB control number 2060–0170 (EPA ICR No. 1432.16).

Burden means the total time, effort, or financial resources expended by persons

to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR Chapter 15.

E. Executive Order 13084: Consultation and Coordination With Indian Tribal Governments

Under Executive Order 13084, EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments, or EPA consults with those governments. If EPA complies by consulting, Executive Order 13084 requires EPA to provide the Office of Management and Budget, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies or matters that significantly or uniquely affect their communities.''

Today's proposed rule does not significantly or uniquely affect the communities of Indian tribal governments. The proposed rule does not impose any enforceable duties on Indian tribal governments. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

F. Regulatory Flexibility

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. This proposed rule would not have a significant impact on a substantial number of small entities since essential-use allocations are granted to large pharmaceutical manufacturing corporations and not small entities such as small businesses, not-for-profit enterprises or small governmental jurisdictions.

EPA concluded that this proposed rule would not have a significant impact on a substantial number of small entities, therefore, I hereby certify that this action will not have a significant economic impact on a substantial number of small entities. This rule, therefore, does not require a regulatory flexibility analysis.

G. E.O. 13045: Protection of Children from Environmental Health Risks and Safety Risks

Executive Order 13045: ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997) applies to any rule that (1) is determined to be ''economically significant'' as defined under E.O. 12866, and (2) concerns an environmental health and safety risk that EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the Agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the Agency.

This rule is not subject to E.O. 13045 because it does not involve decisions intended to mitigate environmental health or safety risks.

H. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (''NTTAA''), Pub. L. 104–113, Section 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

This proposed rule does not involve technical standards. Therefore, EPA is not considering the use of any voluntary consensus standards.

List of Subjects in 40 CFR Part 82

Environmental protection, Administrative practice and procedure, Air pollution control, Chemicals, Chlorofluorocarbons, Exports, Hydrochlorofluorocarbons, Imports, Ozone layer, Reporting and record keeping requirements.

Dated: November 16, 1998.

Carol M. Browner,

Administrator.

40 CFR Part 82 is proposed to be amended as follows:

PART 82—PROTECTION OF STRATOSPHERIC OZONE

1. The authority citation for part 82 continues to read as follows:

Authority: 42 U.S.C. 7414, 7601, 7671–7671q.

Subpart A—Production and Consumption Controls

2. Section 82.4(r)(2) is amended by revising the table to read as follows:

§ 82.4 Prohibitions.

* * * * *

(r) * * *

(2) * * *

TABLE I.—ESSENTIAL USES AGREED TO BY THE PARTIES TO THE PROTOCOL FOR 1999 AND ESSENTIAL-USE ALLOWANCES

Company/Entity	Class I Controlled Substance	Quantity (metric tonnes)
(i) Metered Dose Inhalers for Treatment of Asthma and Chronic Obstructive Pulmonary Disease		
International Pharmaceutical Aerosol Consortium (IPAC)[1]–Armstrong Laboratories, Boehringer Ingelheim Pharmaceuticals, Glaxo Wellcome, Rhone-Poulenc Rorer, Schering-Plough Corporation, 3M.	CFC–11	899.5
	CFC–12	2157.4
	CFC–114	183.6
Medisol Laboratories, Inc.	CFC–11	67.3
	CFC–12	115.3
	CFC–114	9.6
Aeropharm Technology, Inc.	CFC–11	80.1
	CFC–12	160.2
Sciarra Laboratories, Inc.	CFC–11	0.5
	CFC–12	1.5
	CFC–114	0.5
(ii) Cleaning, Bonding and Surface Activation Applications for the Space Shuttle Rockets and Titan Rockets		
National Aeronautics and Space Administration (NASA)/Thiokol Rocket	Methyl Chloroform	56.7
United States Air Force/Titan Rocket	Methyl Chloroform	3.4
(iii) Laboratory and Analytical Applications		
Global Exemption (Restrictions in Appendix G Apply)	All Class I Controlled Substances (except Group VI).	([2])

[1] The International Pharmaceutical Aerosol Consortium (IPAC) consolidated requests for an essential-use exemption to be nominated to the Protocol as an agent of its member companies for administrative convenience. By means of a confidential letter to each of the companies listed above, EPA will allocate essential-use allowances separately to each company in the amount requested by it for the nomination.
[2] No quantity specified.

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 67

[Docket No. FEMA–7271]

Proposed Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency, FEMA.

ACTION: Proposed rule.

SUMMARY: Technical information or comments are requested on the proposed base (1% annual chance) flood elevations and proposed base flood elevation modifications for the communities listed below. The base flood elevations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: The comment period is ninety (90) days following the second publication of this proposed rule in a newspaper of local circulation in each community.

ADDRESSES: The proposed base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Matthew B. Miller, P.E., Chief, Hazards Study Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–3461.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA or Agency) proposes to make determinations of base flood elevations and modified base flood elevations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed base flood and modified base flood elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, state or regional entities. These proposed elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

National Environmental Policy Act

This proposed rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Associate Director, Mitigation Directorate, certifies that this proposed rule is exempt from the requirements of the Regulatory Flexibility Act because proposed or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the National Flood Insurance Program. As a result, a regulatory flexibility analysis has not been prepared.

Regulatory Classification

This proposed rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This proposed rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This proposed rule meets the applicable standards of section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR part 67 is proposed to be amended as follows:

PART 67—[AMENDED]

1. The authority citation for part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.4 [Amended]

2. The tables published under the authority of § 67.4 are proposed to be amended as follows:

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
Florida	Blountstown (City), Calhoun County.	Apalachicola River	At South Mayhaw Drive	*53	*57
			At northern corporate limits	None	*61
		Sutton Creek	Upstream side of South Mayhaw Drive	*53	*57
			Upstream side of Sherry Avenue	*56	*57
Maps available for inspection at the Blountstown City Hall, 125 West Central Avenue, Blountstown, Florida.					
Send comments to Mr. Jimmy Hand, Blountstown City Manager, 125 West Central Avenue, Blountstown, Florida 32424.					
Florida	Calhoun County (Unincorporated Areas).	Apalachicola River	At southern county boundary	None	*36
			At northern county boundary	None	*72
		Chipola River	At mouth at Dead Lakes	None	*41
			At county boundary	None	*60
Maps available for inspection at the Calhoun County Building Inspector's Office, 425 East Central Avenue, Room G–35, Blountstown, Florida.					
Send comments to Mr. Duane Capps, Chairman of the Calhoun County Board, 425 East Central Avenue, Blountstown, Florida 32424.					
Illinois	Romeoville (Village), Will County.	Lily Cache Slough	At the upstream side of the Interstate Route 55 culvert.	None	*611
			Approximately 1,400 feet upstream of Weber Road.	None	*617
Maps available for inspection at the Romeoville Village Hall Annex, 17 Montrose Drive, Romeoville, Illinois.					
Send comments to Mr. Fred P. Dewald, Jr., Village of Romeoville President, 13 Montrose Drive, Romeoville, Illinois 60446.					
Illinois	Will County (Unincorporated Areas).	Lily Cache Slough	At the upstream side of the Interstate Route 55 culvert.	None	*611
			Approximately 1,400 feet upstream of Weber Road.	None	*617
Maps available for inspection at the Will County Land Use Department, 501 Ella Avenue, Joliet, Illinois.					
Send comments to Mr. Charles R. Adelman, Will County Executive, 302 North Chicago Street, Joliet, Illinois 60432–1059.					
Massachusetts	Bridgewater (Town), Plymouth County.	Town River	At the confluence with the Taunton River	*33	*30
			At the upstream corporate limits	*49	*48
		Taunton River	Approximately 300 feet downstream of Mill Street.	*31	*30
			At the confluence of the Town and Matfield Rivers.	*34	*30
		Tributary A to Sawmill Brook.	At the confluence with Sawmill Brook	None	*23
			Approximately 100 feet upstream of Colonial Drive.	None	*35
		Sawmill Brook	Approximately 40 feet downstream of SR 18 & 28 (Bedford Street).	*24	*23
			Approximately 4,800 feet upstream of SR 18 & 28 (Bedford Street).	None	*29
		Matfield River	At the confluence with the Taunton River	*33	30
			Approximately 300 feet upstream of Bridge Street.	*35	*34
		South Brook	At the confluence with Town River	*36	*31

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
			Approximately 30 feet downstream of Water Street.	*40	*39
Maps available for inspection at the Town of Bridgewater Department of Inspectional Services, Academy Building, 66 Central Square, Bridgewater, Massachusetts.					
Send comments to Mr. Roger Provost, Chairman of the Town of Bridgewater Board of Selectmen, 64 Central Square, Bridgewater, Massachusetts 02324.					
Mississippi	Lee County (Unincorporated Areas).	Little Coonewah Creek	Approximately 1,250 feet upstream of Natchez Trace Parkway.	None	*292
			Approximately 0.6 mile upstream of Endville Road.	None	*362
		Tributary to Little Coonewah Creek.	At confluence with Little Coonewah Creek.	None	*336
			Approximately 1,950 feet upstream of Dogwood Hills Circle.	None	*359
		Mud Creek	Approximately 0.8 mile upstream of U.S. Route 78.	*270	*271
			Approximately 0.6 mile upstream of Barnes Crossing Road.	None	*278
		Tributary No. 1 to Mud Creek.	Approximately 125 feet upstream of North Veteran's Boulevard.	None	*279
			Approximately 200 feet upstream of Fern Ridge Road upstream crossing.	None	*316
		Town Creek	Approximately 100 feet downstream of confluence of Tulip Creek.	None	*250
			Approximately 0.5 mile upstream of confluence of Tulip Creek.	None	*252
		Tulip Creek	At confluence with Town Creek	None	*250
			Approximately 100 feet upstream of U.S. Route 78.	None	*290
		West Tulip Creek	At confluence with Tulip Creek	None	*279
			Upstream of Elvis Presley Lake Dam	None	*346
Maps available for inspection at the Lee County Courthouse, 201 West Jefferson, Suite A, Tupelo, Mississippi.					
Send comments to Mr. Billy Davis, President of the Lee County Board of Supervisors, P.O. Box 1785, Tupelo, Mississippi 38802.					
Mississippi	Plantersville (Town), Lee County.	Tulip Creek	Approximately 400 feet upstream of railroad.	None	*257
			Just downstream of State Route 6	None	*266
Maps available for inspection at the Plantersville Town Hall, 2587 Main Street, Plantersville, Mississippi.					
Send comments to The Honorable Viola Foster, Mayor of the Town of Plantersville, P.O. Box 507, Plantersville, Mississippi 38862.					
Mississippi	Saltillo (Town), Lee County.	Sand Creek	At Lake Lamar Bruce Road	None	*307
			Approximately 250 feet upstream of Pea Ridge Road.	None	*313
Maps available for inspection at the Saltillo Town Hall, 205 Second Street, Saltillo, Mississippi.					
Send comments to The Honorable W.K. Webb, Mayor of the Town of Saltillo, P.O. Box K, Saltillo, Mississippi 38866.					
Mississippi	Tupelo (City), Lee County.	Tributary No. 2 to Coonewah Creek.	Approximately 1,400 feet downstream of Brooks Street.	None	*279
			At upstream side of Cliff Gookin Boulevard.	None	*307
		Kings Creek	At confluence with Town Creek	*262	*258
			Upstream of Walsh Road	None	*338
		Little Coonewah Creek	Just upstream of Natchez Trace Parkway	None	*292
			Approximately 1,500 feet downstream of Old Chesterville Road.	None	*336
		Mud Creek	At confluence with Town Creek	*262	*259
			Approximately 0.5 mile upstream of Barnes Crossing Road.	None	*278
		Tributary No. 1 to Mud Creek.	At confluence with Mud Creek	None	*268
			Approximately 1,300 feet upstream of North Veteran's Boulevard.	None	*289
		Tributary No. 2 to Mud Creek.	At confluence with Mud Creek	None	*270

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
			Approximately 110 feet upstream of U.S. Route 45 on-ramp.	None	*273
		Russell Creek	At confluence with Little Coonewah Creek.	None	*300
			Approximately 75 feet upstream of Butler Road.	*339	*341
		Town Creek	Approximately 0.5 mile upstream of confluence of Tulip Creek.	None	*252
			Approximately 100 feet upstream of Natchez Trace Parkway.	None	*275
		Tulip Creek	Approximately 0.6 mile upstream of confluence with Town Creek.	None	*253
			At State Route 178	*278	*279
		West Tulip Creek	Approximately 350 feet upstream of confluence with Tulip Creek.	None	*279
			Approximately 0.54 mile downstream of Elvis Presley Lake Road.	None	*300
Maps available for inspection at the Tupelo City Hall, Department of Planning and Community Development, 117 North Broadway, 2nd Floor, Tupelo, Mississippi.					
Send comments to The Honorable Glenn L. McCullough, Jr., Mayor of the City of Tupelo, P.O. Box 1485, Tupelo, Mississippi 38802–1485.					
Mississippi	Verona (Town), Lee County.	Town Creek	Approximately 600 feet upstream of the confluence of Tulip Creek.	None	*251
			Approximately 1,300 feet upstream of the confluence of Tulip Creek.	None	*251
Maps available for inspection at the Verona City Hall, 194 Main Street, Verona, Mississippi.					
Send comments to The Honorable Billy Fred Wheeler, Mayor of the Town of Verona, P.O. Box 416, Verona, Mississippi 38879.					
New York	Ilion (Village), Herkimer County.	Mohawk River	At downstream corporate limits	*395	*394
			Approximately 1.13 miles upstream of corporate limits.	*395	*394
Maps available for inspection at the Village of Ilion Fire Station, Otsego Street, Ilion, New York.					
Send comments to The Honorable Charles Haggerty, Mayor of the Village of Ilion, P.O. Box 270, Ilion, New York 13357.					
North Carolina	Trent Woods (Town), Craven County.	Trent River	At Country Club Road	None	*9
		Tributary	Approximately 100 feet upstream of Canterbury Road.	None	*16
		Jimmies Creek	Approximately 1,100 feet upstream of the confluence with Wilson Creek.	*9	*10
			At Trent Road	*18	*19
Maps available for inspection at the Trent Woods Town Hall, 912 Country Club Drive, Trent Woods, North Carolina.					
Send comments to The Honorable Michael A. Gorman, Mayor of the Town of Trent Woods, P.O. Box 12392, Trent Woods, North Carolina 28561–2392.					
North Carolina	Wilkes County (Unincorporated Areas).	Reddies River	Approximately 530 feet downstream of U.S. Highway 421–A.	*964	*965
			At confluence with Hoopers Branch	None	*997
Maps available for inspection at the Wilkes County Planning Office, 110 North Street, Wilkesboro, North Carolina.					
Send comments to Mr. Gary Page, Wilkes County Manager, 110 North Street, Wilkesboro, North Carolina 28697.					
South Carolina	Cayce (City), Lexington County.	Congaree Creek	At conflence with the Congaree River	*138	*139
			Approximately 2,200 feet upstream of Interstate 26.	*142	*143
		Congaree River	At confluence of Congaree Creek	*138	*139
			Approximately 1,230 feet upstream of Knox Abbott Drive.	*156	*154
Maps available for inspection at the Cayce City Hall, 1800 12th Street Extension, Cayce, South Carolina.					
Send comments to Mr. John Hicks, Cayce City Manager, P.O. Box 2004, Cayce, South Carolina 29171.					
South Carolina	Columbia (City), Lexington County.	Kinley Creek	At downstream corporate limits approximately 50 feet upstream of Harbison Boulevard.	*224	*228
			At upstream corporate limits approximately 1,100 feet downstream of Beaver Dam Road.	*229	*228

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
Maps available for inspection at the City of Columbia Department of Utilities & Engineering, 1225 Laurel Street, Columbia, South Carolina. Send comments to The Honorable Robert D. Coble, Mayor of the City of Columbia, P.O. Box 147, Columbia, South Carolina 29217.					
South Carolina	Lexington (Town), Lexington County.	Fourteen Mile Creek	Approximately 1,150 feet downstream of Park Road.	*353	*352
			Approximately 1,150 feet upstream of Park Road.	None	*363
		Twelve Mile Creek	Approximately 0.64 mile downstream of the confluence of Tributary TM–1.	*244	*243
			Approximately 0.42 mile downstream of Wildlife Road.	None	*318
Maps available for inspection at the Lexington Town Hall, 11 Maiden Lane, Lexington, South Carolina. Send comments to Mr. L. C. Greene, Lexington Town Administrator, 111 Maiden Lane, Lexington, South Carolina 29072.					
South Carolina	Lexington County (Unincorporated Areas).	First Creek	Approximately 550 feet downstream of Dogwood Road.	*170	*168
			Approximately 300 feet upstream of Goodwin Pond Dam.	None	*306
		Kinley Creek	Approximately 25 feet downstream of Piney Grove Road.	*202	*201
			Approximately 150 feet downstream of Beaver Dam Road.	*232	*231
		Congaree Creek	At confluence with the Congaree River ...	*138	*139
			At upstream side of Platt Springs Road ...	None	*288
		Congaree River	At downstream county boundary	None	*135
			At confluence of Broad River and Saluda River.	*158	*156
		Fourteen Mile Creek	Approximately 1,700 feet upstream of Old Chapin Road.	*350	*349
			Approximately 50 feet upstream of Wise Ferry Road.	None	*458
		Lick Fork Branch	At confluence with Red Bank Creek	None	*185
			At downstream side of Kitti Wake Drive Dam.	None	*260
		Red Bank Creek	Approximately 50 feet upstream of confluence with Congaree Creek.	None	*164
			At upstream side of Calk's Ferry Road	None	*380
		Saluda River	At confluence with Congaree River	*158	*156
			Approximately 875 feet upstream of confluence of Double Branch.	*173	*172
		Savana Branch	At confluence with Congaree Creek	*142	*144
			Approximately 100 feet upstream of St. David's Church Road.	None	*288
		Second Creek	At confluence with First Creek	None	*179
			At confluence of Bear Creek	None	*222
		Bear Creek	At confluence with Second Branch	None	*222
			At confluence of Hunt Branch	None	*274
		Hunt Branch	At confluence with Bear Creek	None	*274
			Approximately 350 feet upstream of Darden Pond Dam.	None	*330
		Lake Murray	Entire shoreline within county	None	*363
		Twelve Mile Creek	Approximately 0.83 mile upstream of Corley Mill Road.	*192	*193
			Approximately 0.47 mile upstream of Taylor Mill Pond Dam.	None	*441
		Tributary to Fourteen Mile Creek.	Approximately 550 feet upstream of confluence with Fourteen Mile Creek.	*264	*265
			Approximately 1,880 feet upstream of confluence with Fourteen Mile Creek.	None	*277
Maps available for inspection at the Lexington County Planning Department, 212 South Lake Drive, 5th Floor, Administration Building, Lexington, South Carolina. Send comments to Mr. Bruce Rucker, Chairman of the Lexington County Council, 212 South Lake Drive, Lexington, South Carolina 29072.					
South Carolina	Pine Ridge (Town), Lexington County.	Congaree Creek	Approximately 1,750 feet downstream of confluence with Savana Bridge.	*142	*143
			Approximately 600 feet downstream of Southern Railway Bridge.	*147	*148

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
		First Creek	Approximately 1,125 feet downstream of Dogwood Road.	*170	*168
			Approximately 320 feet upstream of Dogwood Road.	None	*173
		Savana Branch	At confluence with Congaree Creek	*142	*144
			Approximately 650 feet downstream of Old Dunbar Road.	*144	*147
Maps available for inspection at the Pine Ridge Town Hall, 1200 Fish Hatchery Road, West Columbia, South Carolina.					
Send comments to Ms. Sherry Brooks, Pine Ridge Town Administrator, 1200 Fish Hatchery Road, West Columbia, South Carolina 29172.					
South Carolina	South Congaree (Town), Lexington County.	Congaree Creek	Approximately 1,775 feet upstream of Southern Railway.	*150	*151
			Approximately 1,150 feet upstream of the confluence of Red Bank Creek.	None	*165
		First Creek	At confluence with Congaree Creek	*151	*152
			Approximately 400 feet downstream of Dogwood Road.	*173	*170
		Red Bank Creek	At confluence with Congaree Creek	None	*164
Maps available for inspection at the South Congaree Town Hall, 119 West Berry Road, West Columbia, South Carolina.					
Send comments to The Honorable Stokely Cox, Mayor of the Town of South Congaree, 119 West Berry Road, West Columbia, South Carolina 29172.					
South Carolina	West Columbia (City), Lexington County.	Saluda River	Approximately 4,800 feet upstream of confluence with Congaree River.	*158	*156
			Approximately 300 feet upstream of USGS Gage No. 2–1690.	*170	*169
		Congaree River	Approximately 1,250 feet upstream of Knox Abbot Drive.	*156	*154
			Approximately 1,200 feet upstream of Meeting Street.	*158	*156
Maps available for inspection at the West Columbia City Hall, Zoning Department, 1053 Center Street, West Columbia, South Carolina.					
Send comments to The Honorable Mark Rish, Mayor of the City of West Columbia, 1053 Center Street, West Columbia, South Carolina 29169.					
Tennessee	Murfreesboro (City), Rutherford County.	Bushman Creek	Approximately 1,100 feet upstream of Osborne Lane.	*561	*560
			Approximately 250 feet downstream of New Lascassas Road.	*585	*583
		Sinking Creek	Approximately 0.88 mile upstream of confluence with West Fork Stones River.	*549	*548
			At downstream side of Ewing Boulevard	*611	*610
		Unnamed Tributary of West.	At confluence with West Fork Stones River.	*592	*589
		Fork Stones River	Approximately 0.6 mile upstream of confluence.	*592	*589
		West Fork Stones River	Approximately 0.5 mile upstream of Mason Drive.	*577	*576
			Approximately 0.5 mile upstream of State Route 99.	*597	*596
		Lytle Creek	Approximately 1,200 feet downstream of Old Fort Parkway.	*580	*579
			Approximately 100 feet upstream of Old Fort Parkway.	*581	*580
Maps available for inspection at the Murfreesboro City Hall, Planning Department, 111 West Vine Street, Murfreesboro, Tennessee.					
Send comments to The Honorable Joe B. Jackson, Mayor of the City of Murfreesboro, P.O. Box 1139, Murfreesboro, Tennessee 37133–1139.					
Tennessee	Rutherford County (Unincorporated Areas).	Bushman Creek	Approximately 1,750 feet upstream of Compton Road.	*547	*546
			Approximately 1,400 feet upstream of New Lascassas Road.	*591	*589
		Unnamed Tributary of West.	Approximately 1,000 feet downstream of State Route 99.	*592	*589
		Fork Stones River	Approximately 370 feet downstream of Cason Lane.	*592	*591

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
		West Fork Stones River ...	Approximately 0.5 mile upstream of Mason Drive.	*577	*576
			Approximately 0.5 mile upstream of State Route 99.	*597	*596
Maps available for inspection at the Rutherford County Engineering Department, 1 Public Square South, Room 204, Murfreesboro, Tennessee.					
Send comments to Ms. Nancy R. Allen, Rutherford County Executive, County Courthouse, Public Square, Room 101, Murfreesboro, Tennessee 37130.					
Wisconsin	Baraboo (City), Sauk County.	Baraboo River	Approximately 1,700 feet downstream of Manchester Street.	*818	*819
			Approximately 400 feet downstream of Shaw Street.	*846	*845
Maps available for inspection at the City of Baraboo Engineering Department, 135 4th Street, Baraboo, Wisconsin.					
Send comments to The Honorable Dean D. Steinhorst, Mayor of the City of Baraboo, 135 Fourth Street, Baraboo, Wisconsin 53913.					
Wisconsin	Ironton (Village), Sauk County.	Little Baraboo River	At downstream corporate limits	None	*903
			At upstream corporate limits	None	*904
Maps available for inspection at the Ironton Community Center, 290 Main Street, LaValle, Wisconsin.					
Send comments to Mr. Dwight Denman, Ironton Village President, P.O. Box 57, LaValle, Wisconsin 53941.					
Wisconsin	Lake Delton (Village), Sauk County.	Wisconsin River	At downstream corporate limits	None	*824
			At upstream corporate limits	None	*825
Maps available for inspection at the Lake Delton Village Office, 50 Wisconsin Dells Parkway South, Lake Delton, Wisconsin.					
Send comments to Mr. Frank Kaminski, Lake Delton Village President, P.O. Box 87, Lake Delton, Wisconsin 53940.					
Wisconsin	LaValle (Village), Sauk County.	Baraboo River	Approximately 2,700 feet upstream of State Route 33.	None	*892
			Approximately 2,075 feet upstream of State Route 58.	*899	*894
Maps available for inspection at the LaValle Village Office, 103 West Main Street, LaValle, Wisconsin.					
Send comments to Mr. Duane Nobs, LaValle Village President, P.O. Box 13, LaValle, Wisconsin 53941.					
Wisconsin	Merrimac (Village), Sauk County.	Wisconsin River	At downstream corporate limits	None	*775
			At upstream corporate limits	None	*776
Maps available for inspection at the Merrimac Village Hall, 100 Cook Street, Merrimac, Wisconsin.					
Send comments to Mr. Alan Shanks, Merrimac Village President, 100 Cook Street, P.O. Box 26, Merrimac, Wisconsin 53561.					
Wisconsin	Muscoda (Village), Grant and Iowa Counties.	Wisconsin River	Downstream corporate limits	None	*678
			Upstream corporate limits	None	*680
Maps available for inspection at the Muscoda Village Hall, 206 North Wisconsin Avenue, Muscoda, Wisconsin.					
Send comments to Mr. Larry J. Miller, Muscoda Village President, 206 North Wisconsin Avenue, Muscoda, Wisconsin 53573.					
Wisconsin	North Freedom (Village), Sauk County.	Baraboo River	Approximately 0.53 mile upstream of the downstream crossing of the North Western railroad.	*865	*864
			Approximately 1.08 miles upstream of Mid-Continent Railway.	*868	*867
Maps available for inspection at the North Freedom Village Office, 103 North Maple, North Freedom, Wisconsin.					
Send comments to Mr. Oscar Baumgarten, North Freedom Village President, P.O. Box 300, North Freedom, Wisconsin 53951.					
Wisconsin	Plain (Village)	Honey Creek	Approximately 1,000 feet northeast of the intersection of Main Street and Bridge Road.	None	*799
Maps available for inspection at the Plain Village Clerk's Office, 1015 Cedar Street, Plain, Wisconsin.					
Send comments to Mr. William Gruber, Plain Village President, Village Hall, P.O. Box 15, Plain, Wisconsin 53777.					
Wisconsin	Prairie du Sac (Village), Sauk County.	Wisconsin River	At downstream corporate limits	None	*748
			At upstream corporate limits	None	*749

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
Maps available for inspection at the Prairie du Sac Village Hall, 280 Washington Street, Prairie du Sac, Wisconsin.					
Send comments to Ms. Cheryl Sherman, Prairie du Sac Village President, 280 Washington Street, Prairie du Sac, Wisconsin 53578.					
Wisconsin	Reedsburg (City), Sauk County.	Baraboo River	Approximately 400 feet upstream of Golf Course Road.	None	*876
			Approximately 1 mile upstream of State Route 23/33.	*881	*880
Maps available for inspection at the Reedsburg City Hall, 134 South Locust Street, Reedsburg, Wisconsin.					
Send comments to The Honorable Carl Steolte, Mayor of the City of Reedsburg, 134 South Locust Street, P.O. Box 490, Reedsburg, Wisconsin 53959.					
Wisconsin	Rock Springs (Village), Sauk County.	Baraboo River	Approximately 1,480 feet downstream of State Highway 136 (East Broadway).	*871	*870
			At downstream side of Chicago and Northwestern (approximately 3,400 feet upstream of confluence with Narrows Creek).	*872	*871
		Narrows Creek	At the confluence with the Baraboo River	*871	*870
			Approximately 1,400 feet downstream of State Route 154.	*872	*870
Maps available for inspection at the Rock Springs Village Hall, 110 East Broadway, Rock Springs, Wisconsin.					
Send comments to Mr. Harlan H. Behake, Rock Springs Village President, P.O. Box 26, Rock Springs, Wisconsin 53961.					
Wisconsin	Sauk City (Village), Sauk County.	Wisconsin River	At downstream corporate limits	None	*743
			At upstream corporate limits	None	*748
Maps available for inspection at the Sauk City Village Hall, 726 Water Street, Sauk City, Wisconsin.					
Send comments to Ms. Vicki Breunig, Sauk City Village Administrator, 726 Water Street, Sauk City, Wisconsin 53583.					
Wisconsin	Sauk County (Unincorporated Areas).	Seeley Creek	At confluence with Baraboo River	*865	*864
			Approximately 0.5 mile upstream of County Highway W.	*865	*864
		Little Baraboo River	At confluence with Baraboo River	*895	*892
			Approximately 160 feet downstream of State Route 58.	*895	*894
		Narrows Creek	At the confluence with Narrows Creek	*915	*914
		Split Flow	Approximately 6,400 feet upstream of the confluence with Narrows Creek.	None	*925
		Wisconsin River	Approximately 1,000 feet downstream of State Route 130.	None	*701
			Just downstream of Kilbourn Dam	*830	*827
		Narrows Creek	Approximately 0.60 mile upstream of the confluence with the Baraboo River.	*871	*870
			Just downstream of State Route 154	*925	*924
		Baraboo River	At county boundary (Sauk/Columbia county line) approximately 2.55 miles downstream of State Route 33.	*803	*806
			Approximately 0.56 mile upstream of County Road G.	None	*910
Maps available for inspection at the Sauk County Courthouse, 510 Broadway, Baraboo, Wisconsin.					
Send comments to Mr. Melvin Rose, Sauk County Board Chairman, 505 Broadway Street, Baraboo, Wisconsin 53913.					
Wisconsin	Spring Green (Village), Sauk County.	Wisconsin River	Approximately 1.3 miles downstream of State Highway 23 bridge.	None	*710
			Approximately 500 feet upstream of State Highway 23 bridge.	None	*712
Maps available for inspection at the Spring Green Village Hall, 112 West Monroe Street, Spring Green, Wisconsin.					
Send comments to Mr. James Krey, Spring Green Village President, 112 West Monroe Street, Box 158, Spring Green, Wisconsin 53588.					
Wisconsin	West Baraboo (Village), Sauk County.	Baraboo River	Approximately 1,350 feet downstream of Shaw Street.	*844	*843
			Approximately 0.4 mile upstream of U.S. Route 12.	*853	*854

State	City/town/county	Source of flooding	Location	#Depth in feet above ground. *Elevation in feet (NGVD)	
				Existing	Modified
Maps available for inspection at the West Baraboo Village Hall, 500 Cedar Street, Baraboo, Wisconsin. Send comments to Mr. Scott Alexander, West Baraboo Village President, 500 Cedar Street, P.O. Box 261, Baraboo, Wisconsin 53913.					
Wisconsin	Wisconsin Dells (City), Sauk and Columbia Counties.	Wisconsin River	At downstream corporate limits	*826	*824
			At downstream side if Kilbourn Dam	*830	*827
Maps available for inspection at the Wisconsin Dells City Hall, 300 La Crosse Street, Wisconsin Dells, Wisconsin. Send comments to The Honorable Craig Case, Mayor of the City of Wisconsin Dells, 300 La Crosse Street, Wisconsin Dells, Wisconsin 53965.					

(Catalog of Federal Domestic Assistance No. 83.100, ''Flood Insurance.'')

Dated: November 10, 1998.

Michael J. Armstrong,

Associate Director for Mitigation.

[FR Doc. 98–31042 Filed 11–19–98; 8:45 am]

BILLING CODE 6718–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Cactus Ferruginous Pygmy-owl Take Guidance and Survey Protocol; Extension of Comment Period

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Extension of two public comment periods.

SUMMARY: The U.S. Fish and Wildlife Service (Service) provides notice that it is extending the public comment periods to allow continued public input on the take guidance and survey protocols for the cactus ferruginous pygmy-owl (*Glaucidium brasilianum cactorum*). The take guidance is for use in determining if take of the cactus ferruginous pygmy-owl may result from activities within areas occupied by the species in Arizona. Two survey protocols are proposed—one for determining presence of the species within known historic range in Arizona, and another for gathering information on the species' distribution, occurrence, and numbers. Notices of availability and comment periods were previously published on September 16, 1998 (63 FR 49539) and August 13, 1998 (63 FR 43362 and 43363). This species is listed as endangered in Arizona under the U.S. Endangered Species Act.

DATES: Written comments should be received by March 14, 1999.

ADDRESSES: Persons wishing to review either the cactus ferruginous pygmy-owl take guidance or survey protocol may access either at the world wide web site of the Southwest Region of the Service at http://ifw2es.fws.gov/arizona/, or obtain copies by contacting the U.S. Fish and Wildlife Service, Arizona Ecological Services Field Office, 2321 W. Royal Palm Road, Suite 103, Phoenix, Arizona 85021–4951 or by calling the Field Office at (602) 640–2720. Documents will also be available for public inspection by written request, by appointment only, during normal business hours (7:30 to 4:30), U.S. Fish and Wildlife Service, Phoenix, Arizona. Written data or comments concerning the cactus ferruginous pygmy-owl take guidance or survey protocol should be submitted to the Field Supervisor, Arizona Ecological Services Field Office, Phoenix, Arizona (see address above).

FOR FURTHER INFORMATION CONTACT: Tom Gatz, Acting Field Supervisor, Arizona Ecological Services Field Office in Phoenix, Arizona at (602) 640–2720.

SUPPLEMENTARY INFORMATION:

Background

The cactus ferruginous pygmy-owl was listed by the Service as an endangered species in Arizona on March 10, 1997, based on extensive population declines within its historic range in the state. The pygmy-owl, a small reddish-brown owl, nests in a cavity in a tree or large columnar cactus. The species was once common to abundant in riparian forests, mesquite-cottonwood woodlands, and desertscrub habitats in central and southern portions of the state. It is still considered a potential inhabitant of riparian areas, where this extremely limited vegetative community still occurs, and is found in upper Sonoran Desert habitats usually consisting of dense ironwood, mesquite, acacia, bursage, and saguaro cacti, with understory vegetation of smaller trees and shrubs.

On August 13, 1998, the Service published two notices of availability and opening of public comment periods for cactus ferruginous pygmy-owl survey protocol (63 FR 43362) and taking guidance (63 FR 43363). The comment periods closed on September 14, 1998. The comment periods were extended until November 14, 1998, with a September 16, 1998, notice (63 FR 49539).

Take Guidance

Urban and suburban development within the remaining appropriate habitat of the pygmy-owl is ongoing. These and other actions may result in take of the species. The Endangered Species Act and implementing regulations found at 50 CFR 17.21 and 17.31 set forth a series of general prohibitions that apply to all endangered and threatened wildlife, respectively. These prohibitions, in part, make it illegal for any person subject to the jurisdiction of the United States to take (includes harass, harm, pursue, hunt, shoot, wound, kill, trap, or collect or to attempt any of these). Regulations at 50 CFR 17.3 define the terms ''harm'' and ''harass'' as used under the definition of ''take.'' ''Harm'' is defined as an act which actually kills or injures wildlife. Such acts may include significant habitat modification that impairs essential behavioral patterns, including breeding, feeding, or sheltering. ''Harass'' is defined as an intentional or negligent act or omission which creates a likelihood of injury to wildlife by annoying it to such an extent as to significantly disrupt normal behavior patterns, including, but not limited to, breeding, feeding, or sheltering.

Permits may be issued to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Such permits are available for scientific purposes, to enhance the propagation or survival of the species, and/or for incidental take in connection with otherwise lawful activities.

At the time of listing the owl, the Service provided a partial listing of activities that could potentially harm, harass, or otherwise take the pygmy-owl. These included—

(1) Removal of nest trees;

(2) Removal of a nest box in use by the pygmy-owl;

(3) Clearing or significant modification of occupied habitat, whether or not the nest tree is included;

(4) Sustained noise disturbance during the breeding season;

(5) Pursuit or harassment of individual birds;

(6) Frequent or lengthy low-level flights over occupied habitat during the breeding season;

(7) Severe overgrazing that results in the removal of understory vegetation.

In furtherance of the Service's policy to provide information concerning what activities may be considered take of the pygmy-owl, the Service is making available information to aid both Federal and non-Federal entities in determining when a take situation may occur.

Survey Protocol

The Fish and Wildlife Service (Service) proposes a survey protocol for determining the presence of the endangered cactus ferruginous pygmy-owl (*Glaucidium brasilianum cactorum*) within known historic range of the species in Arizona. The proposed survey protocol comes in two versions depending on its use: the first is for use in determining if cactus ferruginous pygmy-owls are present on specific project sites where an activity is proposed; the second is for use in gathering information on distribution, occurrence, and numbers of pygmy-owls over more extensive areas of its historic range in Arizona. This proposed protocol is founded on procedures established by the Arizona Game and Fish Department in 1993. The proposed protocol incorporates modifications found to be appropriate following 5 years of field application. Differences between the 1993 protocol and the current proposed protocol include a reduction in the survey period from 9 months (September through May) to 6 months (January through June); and an increase in surveys from one to three, with 30 days between each of the three surveys preferred, but a minimum of 15 days required. At least one survey must occur between February 15 and April 15. In reviewing determinations of pygmy owl presence or absence, the Service will require the implementation of the protocol for two consecutive years (rather than one year) prior to actions that may impact the owls or their habitats.

The existing protocol will remain in use and in effect until the public comment period is closed and the Service has evaluated the comments from the public.

The Service has submitted the protocol to recognized species and technical experts for peer review to ensure a scientifically sound basis for determination of the presence of the species within its known range.

The Service will regularly review and modify, as necessary, the survey protocol to ensure that the best available scientific information is incorporated into the prescribed methodology.

Overall Purpose

The Service extends the public comment period to ensure that adequate time is available for the public to provide additional information to more adequately understand the occurrence and biology of the cactus ferruginous pygmy-owl in central and southern Arizona. Until more complete scientific information is available, the Service believes that the use of the take guidance document and the proposed survey protocol document will protect the pygmy-owl while allowing carefully considered development to proceed and will provide the most biologically valid data upon which to determine habitat use and occupancy by the pygmy-owl.

Author: The primary author of this document is Leslie Dierauf, Conservation Biologist, Regional Office.

Authority: The authority for this action is the Endangered Species Act (16 U.S.C. 1532 *et seq.*).

Dated: November 9, 1998.

Geoffery L. Haskett,

Regional Director, Region 2, Albuquerque, New Mexico.

[FR Doc. 98–30533 Filed 11–19–98; 8:45 am]

BILLING CODE 4310–55–U

Notices

Federal Register
Vol. 63, No. 224
Friday, November 20, 1998

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[TM–98–00–8]

Notice of a Teleconference Meeting of the National Organic Standards Board

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, as amended, the Agricultural Marketing Service (AMS) announces a forthcoming Teleconference meeting of the National Organic Standards Board (NOSB).

DATES: December 7, 1998, at 2:00 p.m. to 3:30 p.m. Eastern Standard Time (EST). You must register in advance if you want to be present on the teleconference call, no later than 12:00 p.m. EST November 30, 1998. Comments to be considered by the NOSB prior to the teleconference, should be received by November 30, 1998.

FOR FURTHER INFORMATION CONTACT: Keith Jones, Program Manager, Room 2945 South Building, U.S. Department of Agriculture, AMS, Transportation and Marketing, National Organic Program, P.O. Box 96456, Washington, DC 20090–6456; telephone (202) 720–3235; Fax (202) 205–7808; or by e-mail: t__keith__jones@usda.gov.

SUPPLEMENTARY INFORMATION: Section 2119 (7 U.S.C. 6518) of the Organic Foods Production Act of 1990 (OFPA), as amended (7 U.S.C. 6501 *et seq.*), requires the establishment of the NOSB. The purpose of the NOSB is to assist in the development of standards for substances to be used in organic production and to advise the Secretary on any other aspects of the implementation of the OFPA. The NOSB met for the first time in Washington, DC, in March 1992 and currently has six committees working on various aspects of the program. The committees are: Crops Standards; Processing, Labeling and Packaging; Livestock Standards; Accreditation; Materials; and International Issues. In August 1994, the NOSB provided its initial recommendations for the National Organic Program (NOP) to the Secretary of Agriculture and since that time has submitted 30 addenda to its recommendations, and reviewed more than 170 substances for inclusion on the National List of Allowed and Prohibited Substances. The last meeting of the NOSB was held in July 1998, in Washington, DC. The Department of Agriculture (USDA) published its proposed rule in the **Federal Register** on December 16, 1997 (62 FR 65849). An extension of the comment period on the proposed rule was published in the **Federal Register** on February 9, 1998 (63 FR 6498). The comment period was extended until April 30, 1998. The USDA published for public comment three issue papers in the **Federal Register** (63 FR 57624) on October 28, 1998. The papers addressed certain issues raised during the National Organic Program's proposed rule comment period. The issue papers are: Issue paper 1. Livestock Confinement in Organic Production Systems; Issue Paper 2. The Use of Antibiotics and Parasiticides in Organic Livestock Production; and Paper 3. Termination of Certification by Private Certifiers. Comments received on these papers will be considered during the development of a revised National Organic Program proposed rule.

Purpose and Agenda

The NOSB will conduct a public meeting by teleconference on Friday, December 7, 1998, from 2:00 p.m. to 3:30 p.m. EST inclusive. After the teleconference, the NOSB will make its final recommendations to the Secretary of Agriculture on the above described issue papers.

Type of Meeting

The teleconference meeting will be open to the public. If you wish to be present on the teleconference call you must register in advance to receive the dial-in number (teleconference lines are limited and are available on a first come, first served basis). Please contact Karen Thomas at: (202) 720–3252 or fax: (202) 205–7808 with your name, company name, and telephone number, *no later than* 12:00 p.m. EST November 30, 1998, if you want to be present on the teleconference call. Opportunities for oral comment will be given at the beginning of the call and will be limited to no more than two minutes per speaker and no more than 20 minutes total for the public comment period. Public statements presented at the teleconference meeting should not repeat prior oral or written statements made to USDA by a commenter on the Issue Papers.

In its October 28, 1998 **Federal Register** Notice, USDA established December 14, 1998 as the last date for submission of comments on the Issue Papers. Persons, however, who want the NOSB to consider their comments prior to the teleconference, should submit them to USDA by November 30, 1998 (address above) and indicate that they are being submitted for the December 7, 1998 NOSB teleconference. All comments on the issue papers received by USDA by December 14, 1998, will be considered by it.

Copies of the meeting agenda can be obtained from Karen Y. Thomas at (202) 720–3252 or at the above fax number and copies of the issue papers that will be discussed can be obtained from Keith Jones using the contact information listed at the beginning of this notice. Minutes of the meeting will be available through Keith Jones. All of this information is also available through the NOP web page at: www.ams.usda.gov/nop.

Dated: November 16, 1998.

Eileen S. Stommes,

Deputy Administrator, Transportation and Marketing.

[FR Doc. 98–31185 Filed 11–19–98; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Forest Service

Pilgrim Project, Tahoe National Forest, Sierra County, CA

AGENCY: Forest Service, USDA.

ACTION: Notice; cancellation of intent to prepare an environmental impact settlement.

SUMMARY: On May 22, 1997, a notice was published in the **Federal Register** (at 62 FR 28002–28003) stating that an

environmental impact statement (EIS) would be prepared for proposed timber harvest, plantation thinning, fuels reduction, and wildlife habitat improvement projects for areas in the Wolf/Kanaka/Indian Creek and Middle Yuba River watersheds. On March 20, 1998, a revised notice of intent to prepare an environmental impact statement was published in the **Federal Register** (at 63 FR 13620) that modified the scope of the EIS to just address vegetation management actions and directly connected activities such as fuels treatment and reduction, timber harvesting, and road construction and reconstruction. That notice is hereby cancelled.

After scoping and receiving public comments, we reevaluated and redesignated our proposal so that the proposed activities are now not considered major actions that would significantly affect the quality of the human environment. As a result, we are now preparing an environmental assessment instead of an environmental impact statement.

DATES: This action is effective November 20, 1998.

FOR FURTHER INFORMATION CONTACT: Gary Fildes, Inderdisciplinary Team Leader, Downieville Ranger District, Tahoe National Forest, 15924 Highway 49, Camptonville, CA 95922, (530) 288–3231.

Dated: November 12, 1998.

Steven T. Eubanks,

Forest Supervisor.

[FR Doc. 98–31006 Filed 11–19–98; 8:45 am]

BILLING CODE 3410–11–M

DEPARTMENT OF AGRICULTURE

Forest Service

Sierra Nevada Forest Plan Amendment Project EIS

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare an environmental impact statement.

SUMMARY: The Department of Agriculture, Forest Service, Regions 4 and 5 will prepare an environmental impact statement (EIS) to amend eleven National Forest Land and Resource Management Plans and the Regional Guides for the Intermountain and Pacific Southwest Regions in response to changed circumstances and new information resulting from the report of the Sierra Nevada Ecosystem Project, the Sierra Nevada Science Review, and the Summary of Existing Management Direction. The Land and Resource Management Plans to be amended encompass the Humboldt-Toiyabe, Modoc, Lassen, Plumas, Tahoe, Eldorado, Stanislaus, Sierra, Sequoia, and Inyo National Forests, and the Lake Tahoe Basin Management Unit.

DATES: The public is asked to provide any additional information they believe the Forest Service may still not have at this time, and to submit any issues (points of concern, debate, dispute or disagreement) regarding potential effects of the proposed action or alternatives by January 9, 1999.

ADDRESSES: Send written comments to Steve Clauson, EIS Team Leader, USDA Forest Service, Sierra Nevada Framework Project, Room 419, 801 ''I'' Street, Sacramento, CA 95814.

FOR FURTHER INFORMATION: Contact Steve Clauson, EIS Team Leader, USDA Forest Service, Sierra Nevada Framework Project, Room 419, 801 ''I'' Street, Sacramento, CA 95814. Phone number—916–492–7554.

SUPPLEMENTARY INFORMATION:

Background

In the Pacific Southwest Region, Region 5 of the Forest Service, a Sierra Nevada-wide planning effort was initiated in 1992 to protect the California spotted owl (CASPO). This planning responded to Forest Service research on the status and viability of the California spotted owl (CASPO Technical Report, 1992). The CASPO report recommended interim management guidelines be adopted to protect California spotted owl populations while a more comprehensive management plan was developed. An environmental assessment to implement interim guidelines was prepared and a Decision Notice approving implementation of interim guidelines was signed on January 13, 1993. To develop a comprehensive management plan, the Forest Service prepared a draft environmental impact statement (EIS) for the comprehensive management of California spotted owl in 1995. A revised draft EIS was scheduled for release in 1996, however new scientific information came to light and work was suspended pending the report of a Federal Advisory Committee (FAC) that was chartered to review the revised draft EIS. The work of the FAC was influenced by the Sierra Nevada Ecosystem Project (SNEP), which produced four volumes of scientific assessments including several papers exploring possible management strategies, and made available large databases and maps for the Sierra Nevada.

The Federal Advisory Committee concluded that the revised draft EIS was inadequate in its current form as either an owl or ecosystem management EIS (''Final Report of the California Spotted Owl Federal Advisory Committee'', USDA, December 1997). The FAC report identified specific critical shortcomings and offered recommendations to address inconsistencies with scientific information, flaws in some key elements of the analysis process, and the need for a more collaborative planning process. The Forest Service has redirected the EIS effort in response to the FAC report and other information.

On July 24, 1998, a team of scientists from the USDA Forest Service, Pacific Southwest Research Station, produced the Sierra Nevada Science Review (USDA Forest Service, Pacific Southwest Research Station, July 24, 1998), a review of current scientific information with attention to issues of urgent priority at Sierra Nevada Range-wide scale. A companion document, the Summary of Existing Management Direction, released on August 11, 1998, summarized existing management direction related to issues brought forward in the Science Review. This new scientific information has implications for existing forest plans, social values, and environmental trends in the Sierra Nevada.

The report of the Sierra Nevada Ecosystem Project concludes: ''Most of the problems of the Sierra can be solved, although the timeframe and degree of solution will differ depending on the problem.'' (''Sierra Nevada Ecosystem Project, Final Report to Congress'', Davis: University of California, Centers for Water and Wildland Resources, 1996.) For many of these problems, a range-wide or multi-forest planning approach is needed.

The Land and Resource Management Plans for the eleven national forests in the Sierra Nevada Range and Modoc Plateau were developed in the 1980's and early 1990's. These plans were independently prepared and adopted in response to concerns at the scale appropriate for each forest. Given the science that recently emerged concerning issues that go beyond the individual forest and ownership boundaries, there is an urgent need to amend the plans to reflect this new information and achieve range-wide consistency. In response to this need, on July 10, 1998 Regional Forester G. Lynn Sprague, in cooperation with Region 4, committed to developing new management direction, where necessary, to address concerns on the Sierra Nevada national forests (63 FR 37314). This EIS is part of the overall Sierra

Nevada Framework for Conservation and Collaboration, which will continue to develop solutions to interagency issues and encourage communication on management of wildlands in the Sierra Nevada Range.

Public Involvement

During 1998, nearly 1,000 people participated in 37 community based workshops to provide their perspectives on the Science Review, the Summary of Existing Management Direction, and other information relevant to the EIS. The majority of the workshops took place in Sierra Nevada communities. A Tribal Summit was held in Tahoe City and a state-wide workshop was held in Davis. Other meetings were held in San Francisco, Los Angeles, and Carson City, Nevada. Written comments were submitted at the workshops, on the Internet, and in letters.

People attending the September and October workshops were asked to respond to two questions: (1) Is there other new science relevant to Sierra Nevada national forest management that would cause us to add to or modify the findings in the Science Review, and (2) in light of the Science Review and other new information, what changes would you suggest for management direction in the Sierra Nevada national forests? Responses to these questions, together with the agency's analysis of the new science, information, and legal requirements, were used in framing the proposed action and possible alternatives presented in this Notice of Intent.

In addition to problems or concerns to be addressed in the EIS, many additional concerns surfaced in September and October that are not appropriate to address in the proposed action. Concurrent with this Notice of Intent, the Forest Service has produced a ''Design Paper'' that documents the agency's proposal for addressing concerns outside the scope of the proposed action. The Design Paper is available on the Internet at www.r5.fs.red.us or by request to the Sierra Nevada Framework Project at the address given in the **FOR FURTHER INFORMATION** section.

Public comments received during this period reflect a wide range of social perspectives. Participants largely agreed on broad conservation principles. There were, however, many different perspectives on how the principles might be implemented. The wide variation of community responses confirmed the need to include local residents, as well as regional and national interests, in the design and refinement of alternatives. Numerous suggestions were made encouraging the Forest Service to work with other federal agencies, Indian Tribes, state and local governments, and organizations to solve Sierra Nevada-wide problems. The recommendations and suggestions received during meeting will be reviewed again during the scoping period.

Each Sierra Nevada national forest will continue dialogues with interested members of the public and other agencies throughout the environmental analysis process. Each forest will host community discussions to explain and hear responses to this Notice of Intent. Workshops will be designed to receive suggestions and recommendations regarding the proposed actions as well as information that could help frame alternatives. Specific locations and dates of the meetings will be posted on the Internet at www.r5.fs.fed.us and in the newspapers of record for each Sierra Nevada national forest.

Scope

The selection of problems for inclusion in the EIS was based on the following criteria: (1) New scientific information is available about the extent, intensity, or duration of the problem, (2) geographic scale is broad, (3) public perception or environmental risk, as judged by the science community, indicates action should be taken now, and (4) the problem is not well addressed elsewhere.

A single EIS amending the eleven forest plans is proposed because: (1) Some problems may only be treatable at a range-wide scale, (2) the public, Indian Tribes, other governmental agencies, and the Forest Service need to consider ways to meet environmental goals common to the eleven forests economically and efficiently, and (3) implementation can be made more accountable and consistent.

Problems that did not meet these criteria will be addressed in the associated activities of the Sierra Nevada Framework. For example, concerns surrounding the Sierra Nevada bighorn sheep can be more immediately resolved within the scope of the existing forest plans by increased attention from the five affected national forests in the southern Sierra Nevada.

Problem identified for action in this EIS are:

1. *Old forest ecosystems and associated species.* Old forest ecosystems have declined in quality, amount and connectivity throughout the Sierra Nevada over the past hundred years. Habitats and/or populations of some animals associated with old-forests, including forest carnivores and the California spotted owl, have declined. No regionally consistent direction for old-forest conservation exists.

2. *Aquatic, riparian, and meadow ecosystems.* These ecosystems are the most degraded of all habitats in the Sierra Nevada. Many aquatic and riparian-dependent species (willow flycatcher and amphibians in particular) and communities are at risk. No regionally consistent direction exists to deal with this urgent problem.

3. *Fire and Fuels.* Wildland fire is both a major threat to life, property and natural resources and a critical natural process in the Sierra Nevada. Fire management planning is outdated and not integrated into forest plans.

4. *Noxious weeds.* There is a rapid spread of invasive, exotic plant species that threaten to crowd out native plants and compromise wildland values. Noxious weeds are spreading throughout California and gaining ground at higher elevations in the Sierra Nevada.

5. *Lower westside hardwood forest ecosystems.* Increasing urban development in lower elevations in the Sierra Nevada has fragmented and decreased the amount of hardwood forests. The public has expressed a desire to maintain the remaining extent of hardwood forests for their ecological roles, biodiversity, aesthetics, cultural resources, and for resource uses such as firewood and forage.

Purpose and Need for Action

The purpose of the proposed action is to improve national forest management direction for five broad problems: (1) Conservation of old-forest ecosystems, (2) conservation of aquatic, riparian, and meadow ecosystems, (3) increased risk of fire and fuels buildup, (4) introduction of noxious weeds, and (5) sustaining hardwood forests. Resolution of these problems will influence and be influenced by social, cultural and economic values. The need is to ensure that national forest management direction accounts for current scientific thinking and public expectations, and is consistent among the eleven national forests in practices, procedures, definitions, standards and guidelines.

Current forests plan direction does not reflect the shift in public values and expectations for goods and services from the Sierra Nevada national forests. As the five problem areas are addressed, there is a need to ensure that changes in the level of natural resource products, services, and values, e.g., forage, timber, wildlife, fish, recreation, wilderness, or water, are identified to respond to public concerns with the certainty of

future forest management products and services. In some cases, the lack of certainty has contributed to false expectations about the capability to provide products and services without diminishing long-term productive capability and without violating legal requirements for clean water, clean air, biological diversity, and endangered species.

Three processes are needed to address the problems identified above: adaptive management, landscape analysis, and collaborative interaction with the public.

Adaptive Management. The purpose is to adjust management direction based on results gained through experience. The need is for monitoring protocols that provide timely, accurate information on outcomes achieved by implementing current management direction. As stated in the report of the Sierra Nevada Ecosystem Project: ''All strategies for improvements are in some ways experiments. Learning as we go and adjusting as necessary work best when we give as much care and planning to measuring the response to new management strategies as we do to implementing them.''

Landscape Analysis. The purpose is to consider how management direction at the scale of the forest plan or higher can be applied given landscape conditions at the watershed or subwatershed scale. The need is to identify a suitable set of landscape analysis protocols so that treatment needs can be identified and project priorities set.

Public Interaction and Collaboration. The purpose is to ensure that citizens can meaningfully participate in the design, implementation and monitoring of management direction. Past planning efforts have followed a traditional model that has public input to the planning process only at prescribed intervals with little collaboration. As the report of the Sierra Nevada Ecosystem Project concludes: ''Collaboration among various agencies, private interests, and public at large in the Sierra is the most significant principle that emerges from the SNEP strategies.''

The following are the specific purposes, by problem area, for taking action.

Old Forest Ecosystems and Associated Species. The purpose of the proposed action is to protect, increase, and perpetuate old forest and hardwood ecosystem conditions including their structure, composition, function, and to ensure the maintenance of biological diversity of these ecosystems including the viability of associated species while meeting people's needs and concerns. This will include reversing the declining trends in abundance of old-forest ecosystems and habitats for species that use old-forests.

Aquatic, Riparian, and Meadow Ecosystems. The purpose of the proposed action is to protect and restore aquatic, riparian and meadow ecosystems of the Sierra Nevada national forests. This direction will ensure the proper functioning, such as stable streambanks and shorelines, of key ecosystem processes, such as nutrient cycling, and continued supplies of high quality water and will ensure the maintenance of biological diversity and the viability of species associated with these ecosystems. The purpose is to: (1) Improve consistency of existing conservation programs, strategies and practices, and (2) establish through landscape analysis, a consistent assessment of watershed condition to determine priorities for the allocation of limited personnel and funds.

Fire and Fuels. The purposes are to: (1) bring greater consistency in fire and fuels management across the national forests and coordinate management strategies with other ownerships and with objectives for Forest Service management of other resources, (2) adjust the goals and objectives in the national forest land management plan direction to reflect the role and consequence of wildland fire, and (3) set priorities for fire management actions to balance the need to restore fire regimes while minimizing the threat fire poses to structures, lives and resources.

Noxious Weeds. The purpose is to provide a strategy to control the rapid spread of invasive exotic plant species, to contain existing weed populations and, where possible, to eradicate them.

Lower Westside Hardwood Forest Ecosystems. The purpose of the proposed action is to provide a management strategy that will result in a sustainable hardwood forest ecosystem in the lower westside of the Sierra Nevada, including the structure, composition, and function to ensure maintenance of biological diversity.

Proposed Action

The proposed action responds to the needs identified above, the reports of the Sierra Nevada Ecosystem Project and the Sierra Nevada Science Review, and concerns raised during public workshops held earlier this year. It also responds to the USDA Forest Service Natural Resource Agenda (on the Internet at www.fs.fed.us/news/agenda), the Final Report of the California Spotted Owl Federal Advisory Committee and the Clean Water Action Plan (delivered to Vice President Gore by EPA and USDA on February 19, 1998).

The proposed action, while addressing the five problem areas, integrates multiple uses such as recreation, grazing, timber harvesting, and public access to the national forest into the actions. Sustainable levels of products and services, reflective of shifting public values and expectations, are an integral part of the proposed action. Employment, economic prosperity, community vitality, and the health of resource-based industries were concerns voiced during public comment. They are relevant to all aspects of the proposed action and will be evaluated as alternatives are prepared.

The proposed action calls for application of adaptive management principles to adjust management direction to future events, changing knowledge, or dynamic social views. Adaptive management involves: (1) Establishing desired outcomes and steps towards achieving them, (2) monitoring to generate new information, (3) adjusting management objectives, and (4) adjusting strategies in response to the new information. The proposed action will contain a monitoring strategy to provide the critical information needed to trigger management adaptations.

The proposed action also calls for analysis of environmental conditions and management possibilities at the watershed and sub-watershed scale to: (1) Link decisions at the project scale to larger scale decisions, (2) link forest plans to the efforts of other agencies, (3) prioritize treatments within the watershed or sub-watershed, and (4) facilitate local collaborative stewardship.

The proposed action will be implemented using a collaborative process to ensure coordination and consideration of the needs of other federal agencies, Indian Tribes, state and local governments and individuals. This involvement will help shape national forest land management direction so that ecosystems are restored and maintained while providing the management consistency that allows for a sustainable level of multiple uses, including recreation, grazing, timber, water, mining, and others.

This process will also assure redemption of the government's trust responsibilities with Indian Tribes and consideration of their expertise, cultural needs; and traditional and contemporary uses.

Section 401 of the 1999 Department of the Interior and Related Agencies

Appropriations Act (the Herger-Feinstein Quincy Library Group Forest Recovery Act), 112 Stat. 2681, directs the Secretary to implement a pilot project on certain federal lands within the Plumas, Lassen and Tahoe National forests. The Forest Service will be issuing a Notice of intent for an environmental impact statement to begin implementation of section 401. We will coordinate the Sierra Nevada Forest Plan Amendment Project Environmental Impact Statement with the environmental impact statement to implement section 401. We would like comments from the public and interested groups concerning the relationship between the two environmental impact statements.

The description of the proposed action for each problem area includes alternative strategies, where they have been identified, that could accomplish the purpose and need for action.

1. Old Forest Ecosystems and Associated Species (Including Forest Carnivores and California Spotted Owl)

The desired condition for Sierra Nevada national forests is to support old forests, which vary by vegetation type at a variety of scales, from individual old conifer or hardwood trees and snags to entire landscapes. Old forest habitat is present in sufficient locations, connectivity, quantities, and quality to sustain viable populations of old forest associated species and allow for seasonal migration of animals. Old forest ecosystems, including associated wildlife, fish, and plant populations, will be resilient to natural disturbance processes such as fire, which serve to sustain ecosystem composition, structure, and function. Management of old forest ecosystems integrates hardwoods and complements the aquatic conservation, fire and fuels, and noxious weeds strategies. Human uses of forests, e.g. recreation, resource uses, and Native American uses, are retained as important considerations for management of old forest ecosystems.

The proposed action is to develop both processes and management standards and guidelines for the California spotted owl and forest carnivores to be integrated with strategies for old forests, aquatic ecosystems, and fire and fuel. These processes, standards, and guidelines would address habitat conservation, modeling, mapping and assessment, and analysis of effects of management actions.

The proposed action is to: (1) Develop consistent old forest definitions by forest type, (2) set mapping standards, (3) adapt management to changing conditions, and (4) standardize large-scale monitoring of old forest ecosystems. The expected result of this action is to increase the acreage supporting old forests and habitat for species that occur there. Two contrasting approaches may be applied to achieve the desired condition.

Landscape Reserve Alternative. The landscape reserve alternative would allocate land as old forest emphasis areas. These reserves would occur over all forest types and include hardwoods as well as conifer-dominated communities. Little to no entry for commercial timber harvest or road building would be allowed in these areas. Prescribed fire would be the primary tool to attain protection and restoration goals. The old forest emphasis areas would be large enough to absorb large-scale natural disturbances, and geographically connected by riparian areas protected in the Aquatic Conservation Strategy to facilitate animal dispersal and contribute toward the continued existence of wide-ranging animals.

Old forest emphasis areas would be selected based upon the following criteria: existing concentrations of old trees; known locations of wildlife, fish and plant populations that require these habitats; low road denisty; habitat for riparian/aquatic species; representativeness of soils, geology, climatic and vegetation conditions; existing wilderness and wild and scenic rivers; likelihood of long-term sustainability given estimated fire conditions.

Outside the old forest emphasis areas, individual large old conifer and hardwood trees, large snags, and concentrations of old trees would be protected wherever they occur in the landscape, except where they pose a safety hazard. Lands would be available for commercial timber harvest and other uses.

Whole Forest Alternative. The whole forest alternative designates the entire hardwood and conifer-dominated forest landscape in the Sierra Nevada for succession towards old forests. Individual large old conifer and hardwood trees and large snags would be protected wherever they occur in the landscape, except where they pose a safety hazard. In roadless areas, concentrations of old trees would be protected by constructing no new roads, and conducting no commercial timber harvest. In roaded areas, concentrations of old trees would primarily be maintained using prescribed fire. Elsewhere in roaded areas, commercial timber harvest, other mechanical treatments, and prescribed fire would be used to accelerate succession toward old forest conditions.

The main differences between the landscape reserve and whole forest alternatives are that under the landscape reserve alternative the location of those reserves would not change over time and no commercial timber harvest would be permitted within the reserves, regardless of current condition. Under the Whole Forest Strategy, no timber harvest would be permitted in existing concentrations of old trees, regardless of location. Two points are common to both strategies: (1) The goal is to increase acreages supporting old forest, and (2) concentrations of old trees would move across the landscape over time in response to large-scale natural or human-generated disturbances.

2. Aquatic, Riparian, and Meadow Ecosystems

The desired condition of the Sierra Nevada national forests will be to provide sustainable aquatic, riparian and meadow ecosystem compositions, structures and functions. Structures include vegetation, flows and stream/lake bottoms. Fire and flooding, and processes such as nutrient cycling, water and sediment flows are within a desired range of variability. Land use activities, such as recreation, hydro-power, grazing, mining, timber harvest, transportation system maintenance and fuel treatments will be managed to enhance and restore the health of these ecosystems. Habitat to support populations of native and desired non-native plant, invertebrate, and vertebrate species will be well-distributed. Watersheds will be connected to each other, allowing fish and wildlife populations to move between them.

The proposed action is to implement an Aquatic Conservation Strategy. This includes a broad-scale assessment to identify the highest quality watersheds, and rare and imperiled wildlife and plant habitats for protection.

Important components of the Aquatic Conservation Strategy will be the integration of existing management practices (i.e., collaboration, restoration, existing watershed conservation practices, adaptive management, monitoring and research), landscape analysis to assess watershed conditions, and establishment of emphasis watersheds and habitats. Criteria for designation of emphasis watersheds and habitats include the presence of native aquatic species; a low level or lack of exotic species; watershed condition; and distribution of, rarity of, and risk to aquatic habitat.

The strategy will include specific standards and guidelines for at-risk frog

and amphibian species. This group includes both foothill (*Rana boylii*) and mountain yellow-legged frog (*Rana muscosa*), California red-legged frog (*Rana aurora draytoni*), Cascade frog (*Rana cascade*), northern leopard frog (*Rana pipiens*), and Yosemite toad (*Bufo canorus*). The standards and guidelines will address protecting both occupied and potential habitat from the adverse effects of grazing, mining, reservoir construction, urbanization and other activities.

The willow flycatcher is currently listed by the State of California as an endangered species. Three subspecies occur within California. Two of these subspecies occur in the Sierra Nevada (*Empidonax traillii brewsteri* and *E. t. adastus*) and are listed as Region 5 Sensitive Species. Standards and guidelines for these species will be a subject of the proposed action. A separate subspecies of willow flycatcher (*E. t. extimus*) is listed as federally endangered, occurs at the southern end of the Sierra Nevada, and is not expected to be addressed or affected by this proposed action.

The proposed action is to protect known and potential willow flycatcher habitat from livestock grazing and other management activities through habitat management guidelines. Specific guidelines could include preventing cattle and sheep grazing in willow flycatcher habitat during the breeding season and managing grazing intensity to avoid adverse impacts to vegetation needed for nesting and foraging.

Also included in the guidelines will be measures to: (1) Promote the improvement and expansion of suitable habitat, (2) minimize the likelihood of nest parasitism by brownheaded cowbirds, and (3) require annual surveys to monitor breeding success and habitat conditions.

Two alternative approaches may be applied to implement the Aquatic Conservation Strategy, however both of these approaches will include the strategy for amphibian species and willow flycatcher as described above.

Range-wide Standards. Under this approach, Sierra Nevada-wide standards and guidelines will be developed to be consistent across the province, forest, watershed and project scales. These include delineation of riparian reserves; location, maintenance and engineering of roads; design of timber harvest units; and grazing, recreation, and fuels treatments.

Site Specific Standards. Under this approach, management activities will be determined only after a landscape analysis identifies actions that are most appropriate and effective. In the absence of site specific standards, range-wide standards and guidelines will apply.

3. Fire and Fuels

The desired condition is to have a cost-effective fire management program that protects natural resources, life, and property from the effects of unwanted wildland fire. Fuels are maintained at levels commensurate with minimizing resource loss from fire while meeting other requirements for overall ecosystem health. Fire, under prescribed conditions, is one of the most important tools for restoration and sustainability of ecosystem diversity and productivity. Fire management is coordinated with the National Park Service, Bureau of Land Management, Indian Tribes, Fish and Wildlife Service, California Department of Forestry and Fire Protection and other agencies and jurisdictions.

The proposal is to implement a fire management plan for each of the eleven national forests that demonstrates consistency with the Federal Wildland Fire Policy and coordinates with the California Fire Plan prepared by the California Department of Forestry and Fire Protection. A fire management plan is a strategic plan that defines a program to manage wildland and prescribed fires and documents implementation strategies for the fire management program in the approved forest plan.

All fire plans will be supplemented by a range-wide, interagency assessment of flammability and fire risk. This assessment will be based on existing interagency mapping of surface fuels and vegetation, on fire history (location and size of historical fires), and will be adjusted using other factors that affect fire behavior such as weather, climatology, slope and aspect. It displays the likelihood that fires will occur and suggests how large and intense they could be under existing conditions.

This assessment will help guide the setting of priorities for wildland fire management and fire hazard reduction. Priorities should include location of areas of high resource values, reintroduction of fire as an ecosystem process, effects on local economies and impacts on air quality.

Two alternative strategies for priority setting are proposed.

Prescribed Fire and Natural Wildland Fire Use With Focused Use of Mechanical Treatments. Treat fuel accumulations and restore ecosystems primarily through the use of prescribed and natural wildlife fire. Use mechanical treatments along the urban wildland interface and major transportation routes.

Prescribed Fire and Natural Wildland Fire With Extensive Use of Mechanical Treatments. Use prescribed and natural wildland fire to maintain treated areas and to reintroduce fire. Where fuel accumulations, smoke management restrictions, or other concerns preclude the use of prescribed fire as a means to deal with fuels management or the risk of high intensity wildfire, use mechanical methods to create a network of interspersed shaded fuelbreaks and area-wide treatments consistent with fire management priorities.

4. Noxious Weeds

The desired condition is for no new populations of noxious weeds. Existing populations are contained and, where possible, eradicated. Employees, users of National Forest System lands, adjacent landowners, and State agencies are aware and informed about noxious weed concerns.

The 1995 Forest Service Manual direction for noxious weed management will be incorporated into all alternatives developed in the EIS. Also, because noxious weed control and eradication is a Region-wide effort, management directions developed for the Sierra Nevada forests will be integrated at the Regional scale and coordinated with other land management agencies in California.

Alternatives will contain management direction to minimize the spread of noxious weed by roadbuilding, livestock use, vehicle use, equipment use and other carriers. California wildland fire fighting agencies would be encouraged to inventory and adopt use of weed-free fire camps. Direction will also be included to ensure weed-free administration sites and that materials brought onto the national forests (e.g., sand, gravel, and pack animal's feed) will be weed-free. All alternatives will include direction to use State certified ''noxious weed-free'' materials as soon as the State program is in place.

Monitoring and inventory programs for noxious weed populations will be tied to monitoring that triggers shifting the nature and intensity of actions. Monitoring results and inventories will be shared across agencies and national forests. The range-wide efficiency of the control program would be periodically evaluated.

5. Lower Westside Hardwood Forest Ecosystems

The desired condition is for the lower westside hardwood forests to be present in sufficient locations, connectivity, quantities, and quality to provide for public uses, resident wildlife fish and acquatic species, sensitive plant species

and seasonal migrants including deer. Fire will be employed to maintain both old tree dominated forests and a mosaic of hardwood stand ages across the landscape. Connectivity between lower elevation hardwood and upper elevation conifer forests will be sufficient to allow for wildlife migration and for natural processes, such as wildland fire, to occur. Collaboration with local land owners and governments, and consultation with tribes and permittees, will be an integral part of managing these areas.

The proposed action is a management strategy that will ensure lower westside hardwood forests are sustained. This strategy complements the old-forest, aquatic conservation, fire and fuels, and noxious weeds strategies. Individual large trees and snags, and concentrations of old trees will be protected consistent with the old-forest ecosystem strategy. A mosaic of hardwood stand ages will be provided through reintroduction of fire, where possible, or through other fuels reduction techniques in compliance with the fire and fuels strategy. Management practices for improving connectivity between hardwood and conifer forests and for reducing the impacts of urban development to hardwood ecosystems will also be included. Viable populations of plants and animals associated with hardwood forests would be sustained, to the extent feasible in light of the fragmentation of these forests. The monitoring strategy will be designed to ensure the management strategy is effective in sustaining lower westside hardwood forests.

Proposed Scoping Process

This Notice of Intent initiates the scoping process whereby the Forest Service will identify the scope of issues to be addressed in the EIS and identify the significant environmental issues related to the proposed action.

Public comment is invited on the proposal to prepare the EIS. Comment is also invited on the relationship between the EIS and section 401 of the 1999 Department of Interior and Related Agencies Appropriations Act (the Herger-Feintstein Quincy Library Group Forest Recovery Act), 112 Stat. 2681.

Community meetings with interested publics will be hosted by each Sierra Nevada national forest during scoping, after release of the Draft EIS, and after release of the Final EIS. Coordination with Federal and State agencies, Tribal governments, and local governments will occur throughout the scoping process.

During December 1998, the eleven national forests will each host workshops designed to explain the Notice of Intent. In January 1999, community workshops will be held to solicit suggestions, recommendations, and comments to help frame alternatives to the proposed action. Workshops will also be held in Los Angeles and San Francisco. Specific locations and dates of the meetings will be posted on the Internet at www.r5.fs.fed.us and in the newspaper of record for each Sierra Nevada national forest.

Decision To Be Made and Responsible Official

The Regional Foresters of Regions 4 and 5 will decide, for their respective Regions, whether or not, and in what manner, to amend the Land and Resource Management Plans for the eleven Sierra national forests; Humboldt-Toiyabe, Modoc, Lassen, Plumas, Tahoe, Eldorado, Stanislaus, Sierra, Sequioa, Inyo, and Lake Tahoe Basin Management Unit. Also, the decision could include a non-significant amendment to the Regional Guides for the Intermountain and Pacific Southwest Regions. The responsible officials are Regional Foresters Jack A. Blackwell, Region 4, USDA Forest Service, Federal Building 324, 25th Street, Ogden, UT 84401 and G. Lynn Sprague, Region 5, USDA Forest Service, 630 Sansome Street, San Francisco, CA 94111.

Coordination With Other Agencies

While the Forest Service is the lead agency with responsibility to prepare this EIS, requests have been made of the U.S. Environmental Protection Agency, U.S. Fish and Wildlife Service, California Department of Forestry and Fire Protection, and California Department of Fish and Game to participate as cooperating agencies (40 CFR Part 1501.6). The Environmental Protection Agency and Fish and Wildlife Service have regulatory responsibilities that could not efficiently be considered without direct involvement; formal consultation responsibilities under the Endangered Species Act will be carried out by having a Fish and Wildlife Service specialist participate as a member of the interdisciplinary team. Cooperation by the National Marine Fisheries Service is being sought. Coordination with the California Department of Fish and Game and the California Department of Forestry and Fire Protection is necessary because some mission responsibilities overlap or are closely aligned with the conservation activities of the Forest Service. Negotiations with the California Department of Parks and Recreation to seek their cooperation is also underway. Each agency will continue to participate as resources and competing demands permit. Other agencies, local and county governments will be invited to comment, as appropriate.

Commenting

A draft environmental impact statement is expected to be available for public review and comment in February 1999; and a final environmental impact statement in July 1999. The comment period on the draft environmental impact statement will be 90 days from the date of availability published in the **Federal Register** by the Environmental Protection Agency.

Comments received in response to this solicitation, including names and addresses of those who comment, will be considered part of the public record on this proposed action and will be available for public inspection. Comments submitted anonymously will be accepted and considered. Additionally, pursuant to 7 CFR 1.27(d), any person may request the agency to withhold a submission from the public record by showing how the Freedom of Information (FOIA) permits such confidentiality. Persons requesting such confidentiality should be aware that, under the FOIA, confidentiality may be granted in only very limited circumstances, such as to protect trade secrets. The Forest Service will inform the requester of the agency's decision regarding the request for confidentiality, and where the request is denied, the agency will return the submission and notify the requester that the comments may be resubmitted with or without name and address.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of draft environmental impact statements must structure their participation in the environmental review of the proposal so that it is meaningful and alerts the agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp.* v. *NRDC,* 435 U.S. 519, 553 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental stage may be waived or dismissed by the courts. *City of Angoon* v. *Hodel,* 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc.* v. *Harris,* 490 F. Supp. 1334 (E.D. Wis. 1980). Because of these court rulings, it

is very important that those interested in this proposed action participate by the close of the 90 day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the final environmental impact statement.

To assist the Forest Service in identifying and considering issues and concerns on the proposed action, comments on the draft environmental impact statement should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the draft environmental impact statement or the merits of the alternatives formulated and discussed in the statement. Reviewers may wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

Dated: November 16, 1998.

Kent Connaughton,

Deputy Regional Forester.

[FR Doc. 98–31022 Filed 11–19–98; 8:45 am]

BILLING CODE 3410–11–M

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed Additions to Procurement List.

SUMMARY: The Committee has received proposals to add to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

COMMENTS MUST BE RECEIVED ON OR BEFORE: December 21, 1998.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Gateway 3, Suite 310, 1215 Jefferson Davis Highway, Arlington, Virginia 22202–4302.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the possible impact of the proposed actions.

If the Committee approves the proposed additions, all entities of the Federal Government (except as otherwise indicated) will be required to procure the commodity and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities. I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and services to the Government.

2. The action will result in authorizing small entities to furnish the commodity and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following commodity and services have been proposed for addition to Procurement List for production by the nonprofit agencies listed:

Commodity

Pad, Fingerprint,
7520–00–117–5627
NPA: Cattaraugus County Chapter, NYSARC, Olean, New York.

Services

Janitorial/Custodial, DLA Baton Rouge Depot, 2695 N. Sherwood Forest Drive, Baton Rouge, Louisiana, NPA: Louisiana Industries for the Disabled, Baton Rouge, Louisiana

Janitorial/Custodial, Portsmouth Naval Shipyard, Building 357, Kittery, Maine, NPA: Goodwill Industries of Northern New England, Portland, Maine.

Beverly L. Milkman,

Executive Director.

[FR Doc. 98–31090 Filed 11–19–98; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from the Procurement List.

SUMMARY: This action adds to the Procurement List a commodity and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes from the Procurement List commodities previously furnished by such agencies.

EFFECTIVE DATE: December 21, 1998.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Crystal Gateway 3, Suite 310, 1215 Jefferson Davis Highway, Arlington, Virginia 22202–4302.

FOR FURTHER INFORMATION CONTACT: Beverly Milkman (703) 603–7740.

SUPPLEMENTARY INFORMATION:

On September 18 and October 9, 1998, the Committee for Purchase From People Who Are Blind or Severely Disabled published notices (63 FR 49896 and 54436) of proposed additions to and deletions from the Procurement List:

Additions

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the commodity and services and impact of the additions on the current or most recent contractors, the Committee has determined that the commodity and services listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the commodity and services to the Government.

2. The action will not have a severe economic impact on current contractors for the commodity and services.

3. The action will result in authorizing small entities to furnish the commodity and services to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodity and services proposed for addition to the Procurement List.

Accordingly, the following commodity and services are hereby added to the Procurement List:

Commodity

Strap, Webbing

5340–00–854–6736

Services

Food Service Attendant

Marine Corps Air Station, Beaufort, South Carolina

Grounds Maintenance

National Institute for Occupational Safety and Health, 1095 Willowdale Road, Morgantown, West Virginia

Janitorial/Custodial

Fort McPherson, Georgia

Janitorial/Custodial

Fort Campbell, Kentucky

Janitorial/Custodial

AMSA #106, Punxsutawney, Pennsylvania

Janitorial/Custodial

Major Charles D. Stoops USARC, Punxsutawney, Pennsylvania

Laundry Service

Department of Veterans Affairs Medical Center, 5600 West Dickman Road, Battle Creek, Michigan

Library Services

Davis-Monthan Air Force Base, Arizona

Microfiche/Microfilm Reproduction

Great Plains Area, Department of Housing and Urban Development (HUD), Chicago, Illinois

This action does not affect current contracts awarded prior to the effective date of this addition or options that may be exercised under those contracts.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action will not have a severe economic impact on future contractors for the commodities.

3. The action will result in authorizing small entities to furnish the commodities to the Government.

4. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the commodities deleted from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Accordingly, the following commodities are hereby deleted from the Procurement List:

Pillow, Bed

7210–00–753–6228

Handle, Mop

7920–00–550–9912
7920–00–550–9911
7920–00–550–9902

Beverly L. Milkman,

Executive Director.

[FR Doc. 98–31091 Filed 11–19–98; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

[Docket No. 981113285–8285–01]

RIN 0693–ZA28

Announcement of Availability of Funds for a Competition—Advanced Technology Program (ATP)

AGENCY: National Institute of Standards and Technology, Technology Administration, Commerce.

ACTION: Notice.

SUMMARY: The Technology Administration's National Institute of Standards and Technology (NIST) announces that it will hold a single fiscal year 1999 Advanced Technology Program (ATP) competition. This single competition will continue ATP's practice of being open to all technology areas, while also capturing the advantage and momentum of focused program planning. Through this single competition strategy, ATP encourages proposals from the many technical terms that have identified synergy between industry needs and ATP funding opportunities, accelerating the pursuit of critical elements of research which were identified in focused program plans. All fiscal year 1999 proposals received will be distributed to technology-specific source evaluation boards in areas such as advanced materials, biotechnology, electronics, information technology, etc. This notice provides general information regarding ATP competitions.

DATES: The proposal due date and other competition-specific instructions will be published in the Commerce Business Daily (CBD) at the time the competition is announced. Dates, times, and locations of Proposers' Conferences held for interested parties considering applying for funding will also be announced in the CBD.

ADDRESSES: Information on the ATP may be obtained from the following address: National Institute of Standards and Technology, Advanced Technology Program, 100 Bureau Drive, Stop 4701, Administration Building 101, Room A407, Gaithersburg, MD 20899–4701.

Additionally, information on the ATP is available on the Internet through the World Wide Web (WWW) at http://www.atp.nist.gov.

FOR FURTHER INFORMATION CONTACT: Requests for ATP information, application materials, and/or to have your name added to the ATP mailing list for future mailings may also be made by:

(a) Calling the ATP toll-free ''hotline'' number at 1–800–ATP–FUND or 1–800–287–3863. You will have the option of hearing recorded messages regarding the status of the ATP or speaking to one of our customer representatives who will take your name and address. If our representatives are all busy when you call, leave a message after the tone. To ensure that the information is entered correctly, please speak distinctly and slowly and spell the words that might cause confusion. Leave your phone number as well as your name and address;

(b) Sending a facsimile (fax) to 301–926–9524 or 301–590–3053; or

(c) Sending electronic mail to atp@nist.gov. Include your name, full mailing address, and phone number.

SUPPLEMENTARY INFORMATION:

Background

The statutory authority for the ATP is Section 5131 of the Omnibus Trade and Competitiveness Act of 1988 (Pub. L. 100–418, 15 U.S.C. 278n), as modified by Pub. L. 102–245. The ATP implementing regulations are published at 15 CFR Part 295, as amended. The Catalog of Federal Domestic Assistance (CFDA) number and program title for the ATP are 11.612, Advanced Technology Program (ATP).

The ATP is a rigorously competitive cost-sharing program designed for the Federal government to work in partnership with industry to foster the development and broad dissemination of challenging, high-risk technologies that offer the potential for significant, broad-based economic benefits for the

nation. Such a unique government-industry research partnership fosters the acceleration not only of dramatic gains in existing industries, but also acceleration of the development of emerging or enabling technologies leading to revolutionary new products, industrial processes and services for the world's markets and work to spawn industries of the 21st century. The ATP provides multi-year funding to single companies and to industry-led joint ventures. The ATP accelerates technologies that, because they are risky, are unlikely to be developed in time to compete in rapidly changing world markets without such a partnership between industry and the Federal government. The ATP challenges industry to take on higher risk (but commensurately higher potential payoff to the nation) projects than they would otherwise. Proposers must provide credible arguments as to the project feasibility.

The funding instrument used in ATP awards is a ''cooperative agreement.'' Through the use of the cooperative agreement, the ATP is designed to foster a government-industry partnership to accomplish a public purpose of support or stimulation. NIST plays a substantial role in providing technical assistance and monitoring the technical work and business progress.

Funding Availability

A total estimated $66 million in first year funding expected to become available from Congressional appropriation, will be used for new awards for the fiscal year 1999 single ATP competition to be announced in the CBD. The actual number of proposals funded under this competition will depend on the quality of the proposals received and the amount of funding requested in the highest ranked proposals. Outyear funding beyond the first year is contingent on the approval of future Congressional appropriations and satisfactory project performance.

Eligibility Requirements, Selection Criteria, and Proposal Review Process

The eligibility requirements, selection criteria, and the proposal review process are discussed in detail in the ATP implementing regulations published at 15 CFR Part 295, as amended, and the ATP Proposal Preparation Kit dated November 1998.

Funding Amounts, Award Period and Cost Sharing (Matching) Requirements

(a) Single company recipients can receive up to $2 million for R&D activities for up to 3 years. ATP funds may only be used to pay for direct costs for single company recipients. Single company recipients are responsible for funding all of their overhead/indirect costs. Small and medium size companies applying as single company proposers are not required to provide cost-sharing of direct costs, however, they may pay a portion of the direct costs in addition to all indirect costs if they wish. Large companies applying as single company proposers, however, must cost-share at least 60 percent of the yearly total project costs (direct plus indirect costs). A large company is defined as any business, including any parent company plus related subsidiaries, having annual revenues in excess of $2.721 billion. (Note that this number will likely change for future competitions and, if so, will be noted in future annual announcements of availability of funds and ATP Proposal Preparation Kits.)

(b) Joint ventures can receive funds for R&D activities for up to 5 years with no funding limitation other than the announced availability of funds. However, ATP funding must be for a minority share of the yearly total project costs. Joint ventures must cost-share (matching funds) more than 50 percent of the yearly total project costs (direct plus indirect costs). Matching funds (cost-sharing) are defined in 15 CFR Part 295.2(l).

(c) Funds derived from Federal sources may not be used to meet the cost-share requirement. Additionally, subcontractors may not contribute towards the cost-share requirement.

Application Forms and Proposal Preparation Kit

A new November 1998 version of the ATP Proposal Preparation Kit is available upon request from the ATP at the address and phone numbers noted in this notice. The Kit is also available on the Internet through the World Wide Web under the heading Publications on the ATP home page http://www.atp.nist.gov. Note that the ATP is mailing the Kit to all those individuals whose names are currently on the ATP mailing list. Those individuals need not contact the ATP to request a copy. The Kit contains proposal cover sheets, other required forms, background material, and instructions for preparing ATP pre-proposals and full proposals. All proposals must be prepared in accordance with the instructions in the Kit.

Submission of Revised Proposals

A proposer may submit a full proposal that is a revised version of a full proposal submitted to a previous ATP competition. NIST will examine such proposals to determine whether substantial revisions have been made. Where the revisions are determined not to be substantial, NIST reserves the right to score and rank, or where appropriate, to reject, such proposals based on reviews of the previous submitted proposal.

Other Requirements

(a) Federal Policies and Procedures. Recipients and subrecipients are subject to all Federal laws and Federal and Department of Commerce policies, regulations, and procedures applicable to Federal financial assistance awards as identified in the cooperative agreement award.

(b) Past Performance. Unsatisfactory performance under prior Federal awards may result in a proposal not being considered for funding.

(c) Pre-award Activities. Pre-award costs may not be incurred by any proposer and are not reimbursable under an ATP award.

(d) No Obligation for Future Funding. If a proposal is selected for funding, NIST has no obligation to provide any additional future funding in connection with that award. Renewal of an award to increase funding or extend the period of performance is at the total discretion of NIST.

(e) Delinquent Federal Debts. No award of Federal funds shall be made to a proposer or recipient who has an outstanding delinquent Federal debt until either the delinquent account is paid in full, a negotiated repayment schedule is established and at least one payment is received, or other arrangements satisfactory to NIST are made.

(f) Name Check Review. All for-profit and non-profit proposers are subject to a name check review process. Name checks are intended to reveal if any key individuals associated with the proposer have been convicted of or are presently facing criminal charges such as fraud, theft, perjury, or other matters which significantly reflect on the proposer's management, honesty, or financial integrity.

(g) Primary Applicant Certification. All primary proposers (including all joint venture participants) must submit a completed form CD–511, ''Certifications Regarding Debarment, Suspension, and Other Responsibility Matters; Drug-Free Workplace Requirements and Lobbying,'' and the following explanation is hereby provided:

(1) Nonprocurement Debarment and Suspension. Prospective participants, as defined at 15 CFR part 26, section 105

are subject to 15 CFR part 26, ''Nonprocurement Debarment and Suspension'' and the related section of the certification form prescribed above applies;

(2) Drug-Free Workplace, Grantees (as defined at 15 CFR part 605) are subject to 15 CFR 26, subpart F, ''Governmentwide Requirements for Drug-Free Workplace (Grants)'' and the related section of the certification form prescribed above applies;

(3) Anti-Lobbying. Persons (as defined at 15 CFR part 28, section 105) are subject to the lobbying provisions of 31 U.S.C. 1352, ''Limitations on use of appropriated funds to influence certain Federal contracting and financial transactions,'' and the lobbying section of the certification form prescribed above applies to applications/bids for grants, cooperative agreements, and contracts for more than $100,000, and loans and loan guarantees for more than $150,000, or the single family maximum mortgage limit for affected programs, whichever is greater; and,

(4) Anti-Lobbying Disclosures. Any proposer that has paid or will pay for lobbying using any funds must submit an SF–LLL, ''Disclosure of Lobbying Activities,'' as required under 15 CFR part 28, Appendix B.

(h) Lower Tier Certification. Recipients shall require proposers/bidders for subgrants, contracts, subcontracts, or other lower tier covered transactions at any tier under the award to submit, if applicable, a completed Form CD–512, ''Certifications Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion—Lower Tier Covered Transactions and Lobbying'' and Form SF–LLL, ''Disclosure of Lobbying Activities.'' Although the CD–512 is intended for the use of primary recipients and should not be transmitted to NIST, the SF–LLL submitted by any tier recipient or subrecipient should be forwarded in accordance with the instructions contained in the award document.

(i) False Statements. A false statement on any application for funding under ATP may be grounds for denial or termination of funds and grounds for possible punishment by a fine or imprisonment as provided in 18 U.S.C. 1001.

(j) Intergovernmental Review. The ATP does not involve the mandatory payment of any matching funds from state or local government and does not affect directly any state or local government. Accordingly, the Department of Commerce has determined that Executive Order 12372, ''Intergovernmental Review of Federal Programs'' is not applicable to this program.

(k) American-Made Equipment and Products. Proposers are hereby notified that they are encouraged, to the greatest extend practicable, to purchase American-made equipment and products with the funding provided under this program in accordance with Congressional intent.

(l) Paperwork Reduction Act. This notice contains collection of information requirements subject to the Paperwork Reduction Act (PRA), which have been approved by the Office of Management and Budget (OMB Control Nos. 0693–0009 and 0348–0046). Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control No.

(m) If a proposer's proposal is judged to be of high enough quality to be invited in for an oral review, ATP reserves the right to submit a list of questions to the proposer that must be addressed at the oral review.

(n) There are certain types of projects that ATP will not fund because they are inconsistent with the ATP mission. These include:

(1) Straightforward improvements of existing products or product development.

(2) Projects that are predominately basic research.

(3) Pre-commercial scale demonstration projects where the emphasis is on demonstration that some technology works on a large scale or is economically sound rather than on R&D.

(4) Projects involving military weapons R&D or R&D that is of interest only to some mission agency rather than to the commercial marketplace.

(5) Projects that ATP believes would likely be completed without ATP funds in the same time frame or nearly the same time frame.

(o) Certain costs that may be allowed in Federal financial assistance programs are not eligible for funding under ATP awards. Section G of the Proposal Preparation Kit lists these costs.

(p) For joint ventures, no costs shall be incurred under an ATP project by the joint venture members until such time as a joint venture agreement has been executed by all of the joint venture members and approved by NIST. NIST will withhold approval until it determines that a sufficient number of members have signed the joint venture agreement. Costs will only be allowed after the execution of the joint venture agreement and approval by NIST.

(q) Research under an ATP project involving vertebrate animals must be in compliance with the National Research Council's ''Guide for the Care and Use of Laboratory Animals'' which can be obtained from National Academy Press, 2101 Constitution Ave., NW, Washington, DC 20055. The Institutional Animal Care and Use Committee (IACUC) associated with the proposing organization(s) must approve all research involving vertebrate animals before Grants Officer review and release of funds.

(r) Research under an ATP project involving human subjects or human tissue must be in compliance with Department of Commerce regulations entitled ''Protection of Human Subjects'', 15 CFR Part 27, which require that recipients whose research involves human subjects maintain appropriate policies and procedures for the protection of human subjects. Currently, NIST does not approve human subjects research that takes place in a foreign country as part of an ATP project. In addition, NIST does not accept foreign sources of human tissue or data, even if the tissue or data may qualify for an exemption under the rule.

Additional Presidential policies, statutes, regulations, and guidelines have been issued concerning types of research activities involving human subjects. NIST may not be directly named in these statutes and regulations; however, in order to assure that research funded by NIST involving human subjects is consistent with national policy, NIST hereby declares that it will fully adhere to these requirements. Therefore, research projects involving the protected classes of human subjects must adhere to the National Institutes of Health (NIH) regulations found at 45 CFR Part 46, Subparts B, C, and D. Protected classes include pregnant women, human in vitro fertilization, fetuses, prisoners, and children. Research projects involving the transplantation of fetal tissue into human subjects must adhere to Section 111 of the NIH Revitalization Act of 1993, 42 U.S.C. 289g–1. In addition, the NIH Revitalization Act of 1993, 42 U.S.C. 289g–2 contains a criminal statute prohibiting all purchases of fetal tissue for valuable consideration whether or not NIH or NIH funding is involved. Fetal research must adhere to Section 498(b) of the Public Health Service Act, 42 U.S.C. 289g. Embryo research must adhere to Section 513 of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act of

1998, Public Law 105–78, 111 Stat. 1467. Research involving xenotransplantation into human subjects must adhere to the FDA guidelines published at 61 FR 49919 (September 23, 1996). All research projects will adhere to the Presidential Directive, 33 Weekly Comp. Pres. Doc. 281 (March 10, 1997), prohibiting the federal conduct and funding of research involving human cloning.

Special Requirements

Research projects involving protected classes of human subjects as defined in 45 CFR Part 46, Subparts B, C, and D (including pregnant women, human in vitro fertilization, fetuses, prisoners, and children) MUST be reviewed and approved by an Institutional Review Board (IRB) that possesses a current assurance which has been approved by the Office of Protection from Research Risk (OPRR), National Institutes of Health (NIH), for federal-wide use, and appropriate for the research in question. No award involving protected classes as defined under 45 CFR Part 46, Subpart B, will be issued until the proposer has certified that an appropriate IRB has made the determinations required under Subpart B, and all other NIST approvals have been completed.

(s) In any invention resulting from work performed under an ATP project in which an ATP recipient has acquired title, NIST has the right, in accordance with 15 CFR 295.8(a)(2) and any supplemental regulations of NIST, to require the recipient, an assignee, or an exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are resealable under the circumstances. If the recipient, assignee, or exclusive licensee refuses such a request, NIST has the right to grant such a license itself if NIST determines that:

(1) Such action is necessary because the recipient or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

(2) Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the recipient, assignee, or licensees;

(3) Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the recipient, assignee, or licensees; or

(4) Such action is necessary because of the requirement that the recipient grant licenses to potential licensees that would be likely to manufacture substantially in the United States or that, under the circumstances, domestic manufacture is not commercially feasible, is not adhered to, or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of the aforementioned requirement.

The preceding information describes NIST's legal rights with regards to patents. However, potential proposers should not interpret these rights as indicating that NIST intends to manage an awardee's intellectual property. Quite the contrary. First of all, these rights only apply to patents resulting from the ATP project itself, and not from work done before or after the ATP project, or other R&D performed by the company in the same time frame that is not part of the ATP-funded tasks. More importantly, the provisions above would ONLY be invoked under very unique circumstances. For example, if an ATP project developed a cure for cancer, but for some strange reason the company chose not to commercialize the technology, the ATP might, only after verifying that the company had no intention of using the technology, invoke provision 2. above and try to find another company willing to take a license and bring the new development to market. In the over 300 projects funded to date, NIST has never had to exercise the rights noted above.

(t) Proposers shall provide sufficient funds in the project multi-year budget for a project audit, including each joint venture participant. Subcontractors/subawardees, including universities, who receive total funding under an ATP project totaling more than $300,000 each are also subject to the audit requirement. A subcontractor/subawardee is defined as an organization which receives a portion of the financial assistance from the recipient/awardee and assists the ATP recipient/awardee in meeting the project goals but does not include procurement of goods and services. It is the responsibility of the recipient to ensure that audits are performed in a timely fashion. Most routine audits can be performed by the recipient's external CPA. However, the Department of Commerce Office of Inspector General (DoC/OIG) and General Accounting Office (GAO) reserve the right to carry out audits as deemed necessary and appropriate. ATP recipients must be willing to submit to audits (e.g., audits of cost-accounting systems, direct-cost expenditures, indirect cost rates, or other periodic reviews) by the DoC/OIG or cognizant Federal agency Inspectors General or GAO. Periodic project audits shall be performed as follows:

(1) For awards less than 24 months, an audit is required at the end of the project.

(2) For 2-, 3-, or 4-year awards, an audit is required after the first year and at the end of the project.

(3) For 5-year awards, an audit is required after the first year, third year, and at the end of the project.

Budgeting for an audit shall be as follows:

(1) Proposers should allocate funds in their proposal budgets under the ''Other'' direct cost category for the project audit. For joint ventures, this must be included in each participant's budget as each participant is responsible for the performance of their own project audit.

(2) If an organization's indirect cost pool includes audit costs, this is acceptable. In these cases, an explanation must be provided in the budget narrative and no audit costs reflected under ''Other'' costs.

(3) If a cognizant Federal agency auditor is resident within the company, the cognizant Federal agency auditor may perform the audit. In these cases, an explanation must be provided in the budget narrative and no audit costs reflected under ''Other'' costs or ''Indirect Costs.''

Audits of all recipients shall be conducted in accordance with Government Auditing Standards (GAS), issued by the Comptroller General of the United States (the Yellow Book). If an ATP recipient is required to have an audit performed in accordance with OMB Circular A–133, Audits of States, Local Government, and Non-Profit Organizations, the annual Circular A–133 audit is deemed to meet the ATP audit requirement.

If an ATP recipient does not have an annual Circular A–133 audit performed, the recipient should follow the following project audit requirements:

(1) Audits for single company recipients shall be conducted using the NIST Program-Specific Audit Guidelines for Advanced Technology Program (ATP) Cooperative Agreements with Single Companies.

(2) Audits for joint venture recipients shall be conducted using the NIST Program-Specific Audit Guidelines for Advanced Technology Program (ATP) Cooperative Agreements with Joint Ventures.

(u) Indirect cost charged to ATP cooperative agreements or used as cost-sharing must be calculated in accordance with an approved indirect cost proposal. If a recipient has established an indirect cost rate with its

cognizant Federal agency (the Federal agency providing the greatest dollars), the recipient must submit a copy of the negotiated agreement to the DoC/OIG for verification. Acceptance of indirect cost rates in excess of 100 percent of direct costs is subject to approval by NIST and the DoC/OIG. If an indirect cost rate(s) has not been negotiated prior to receiving the award, then an indirect cost rate proposal must be submitted to the recipient's cognizant Federal agency within 90 days from the date of the award. Provisional rates provided by the joint venture participant in the indirect cost proposal may be used until approval is obtained or indirect cost rates are negotiated.

(v) All ATP recipients must agree to adhere to the U.S. Export Administration laws and regulations and shall not export or re-export, directly or indirectly, any technical data created with Government funding under an award to any country for which the United States Government or any agency thereof, at the time of such export or re-export requires an export license or other Governmental approval without first obtaining such licenses or approval and the written clearance of the NIST Grants Officer. The Bureau of Export Administration (BXA) shall conduct an annual review for any relevant information about a proposer and/or Recipient. NIST reserves the right to not issue any award or suspend or terminate an existing award in the event that significant adverse information about a proposer or Recipient is disclosed by BXA to the NIST Grants Officer.

Dated: November 16, 1998.

Robert E. Hebner,

Acting Deputy Director, National Institute of Standards and Technology.

[FR Doc. 98–30957 Filed 11–17–98; 2:55 pm]

BILLING CODE 3510–13–M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D.110298A]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Essential Fish Habitat Amendment to the Fishery Management Plans of the U.S. Caribbean

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of availability of an amendment to the fishery management plans of the U.S. Caribbean; request for comments.

SUMMARY: NMFS announces that the Caribbean Fishery Management Council (Council) has submitted its Essential Fish Habitat (EFH) Generic Amendment to the Fishery Management Plans of the U.S. Caribbean (FMPs) for its review, approval, and implementation. Written comments are requested from the public.

DATES: Written comments must be received on or before January 19, 1999.

ADDRESSES: Comments must be mailed to the Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702.

Requests for copies of the amendment, which includes an environmental assessment, should be sent to the Caribbean Fishery Management Council, 268 Munoz Rivera Avenue, Suite 11108, San Juan, Puerto Rico 00918–2577, Phone: 787–766–5926; Fax: 787–766–6239.

FOR FURTHER INFORMATION CONTACT: Georgia Cranmore, 813-570-5305.

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each regional fishery management council to submit any fishery management plan or amendment it prepares to NMFS for review and approval, disapproval, or partial approval. The Magnuson-Stevens Act also requires that NMFS, after receiving an amendment, immediately publish a notice in the **Federal Register** that the amendment is available for public review and comment. This document constitutes such notice for the EFH amendment.

NMFS will consider the public comments received during the comment period in determining whether to approve, disapprove, or partially approve this amendment.

NMFS published guidelines to assist regional fishery management councils in the description and identification of EFH in FMPs, including identification of adverse impacts from both fishing and non-fishing activities on EFH and identification of actions required to conserve and enhance EFH (62 FR 66531, December 19, 1997). These guidelines encourage ecosystem approaches to protecting and conserving EFH. Identification of ecological roles (i.e., prey, competitors, trophic links within foodwebs, and nutrient transfer between ecosystems) should be incorporated into EFH recommendations. The guidelines also specify that sufficient EFH be protected and conserved to support sustainable fisheries and managed species' contribution to a healthy ecosystem.

The Council's EFH generic amendment includes information on important factors in the relationships between species in the fishery management units and their habitats during each of the species' life stages, including eggs, larvae, juveniles, adults, and spawning adults. Available information is not sufficient to provide for the identification of EFH for each species in all FMPs. There are more than 1,149 species of finfish and over 1,170 mollusks reported in Puerto Rico and the U.S. Virgin Islands. The Council has identified, to the extent possible, the environmental, trophic, and biological characteristics of species managed by each FMP prepared by the Council. The Council has emphasized selected species, and in the absence of habitat information, has used them as ''indicators'' of such habitats. Following is a summary of the EFH generic amendment:

1. EFH is identified and described based on areas where various life stages of the 17 selected, managed species and the coral complex commonly occur. The selected species are: Nassau grouper, *Epinephelus striatus*; red hind, *Epinephelus guttatus*; coney, *Epinephelus fulvus*; yellowtail snapper,*Ocyurus chrysurus*; mutton snapper, *Lutjanus analis*; schoolmaster,*Lutjanus apodus*; grey snapper, *Lutjanus griseus*; silk snapper, *Lutjanus vivanus*; butterfly fish, *Chaetodon striatus*; squirrel fish, *Holocentrus ascensionis*; white grunt, *Haemulon plumieri*; queen triggerfish, *Balistes vetula*; sandtilefish, *Malacanthus plumieri*; redtail parrotfish, *Sparisoma chrysopterum*; trunkfish, *Lactophrys quadricornis*; spiny lobster, *Panulirus argus*; and queen conch, *Strombus gigas*.

2. The selected species represent some of the key species under management by the Council. Collectively, these species commonly occur throughout all the marine and estuarine waters of the U.S. Caribbean. EFH for the remaining managed species will be addressed in future FMP amendments, as information becomes available.

3. EFH is defined as everywhere that the selected species commonly occur. Because these species collectively occur in all habitats of the U.S. Caribbean, the EFH of all species combined includes all waters and substrates (mud, sand, shell, rock, and associated biological communities), including coral habitats (coral reefs, coral hard bottoms, and octocoral reefs), sub-tidal vegetation (seagrasses and algae) and adjacent

intertidal vegetation (wetlands and mangroves). Therefore, collectively EFH includes virtually all marine waters and substrates from the shoreline to the seaward limit of the exclusive economic zone.

4. Threats to EFH from fishing and non-fishing activities are identified.

5. Whenever possible, options to conserve and enhance EFH are provided and research needs are identified.

6. No management measures and, therefore, no regulations are proposed at this time. Measures to minimize any identified impacts are deferred to future amendments when the Council has the information necessary to decide if the measures are practicable.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: November 16, 1998.

Dean Swanson,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 98–31085 Filed 11–19–98; 8:45 am]

BILLING CODE 3510–22–F

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection: Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter the ''Corporation''), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Corporation is soliciting comments concerning its proposed Learn and Serve America Project Description Form. This form will be used to collect information on program descriptions and participation levels in service-learning programs supported by funds from the Corporation. The information provided will be used by the Corporation to: (1) measure performance of service-learning programs as required by the Corporation's annual performance plans prepared in response to the Government Performance and Results Act of 1993; (2) improve management and administration of the Learn and Serve America program; (3) inform grantees through the National Service-Learning Clearinghouse about the plans and activities of programs funded by the Corporation.

Copies of the proposed information collection form can be obtained by contacting the office listed below in the address section of this notice.

The Corporation is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section January 19, 1999.

ADDRESSES: Send comments to Corporation for National and Community Service, Office of Learn and Serve America, Attn. Brad Lewis, 8th Floor, 1201 New York Avenue, NW, Washington, DC 20525.

FOR FURTHER INFORMATION CONTACT: Brad Lewis (202) 606–5000, ext. 113.

SUPPLEMENTARY INFORMATION:

I. Background

The Government Performance and Results Act of 1993 requires all federal departments and agencies to prepare annual performance plans for all budget activities. These plans are to contain performance goals and indicators measuring the outcomes and impacts of federal programs. The Corporation's initial performance plan, covering fiscal 1999, contains performance goals for Learn and Serve America relating to the number of student participants and descriptions of service-learning programs. This new data collection effort will provide that information which will be reported to Congress and the public in an annual performance report beginning in March 2000.

In addition, the Corporation has a commitment to support the quality improvement efforts of its grantees through monitoring, training, and technical assistance. A major part of this effort is carried out through the Learn and Serve America National Service-Learning Clearinghouse. The Clearinghouse is charged with compiling and sharing information with the Corporation's grantees and the public concerning how to plan, implement, and manage service-learning programs and activities.

Furthermore, until this new information collection effort is in place, the national program office for Learn and Serve America will have no systematic means by which to compile quantitative information on grantee and sub-grantee performance for all recipients of its funding. Presently, grantees' progress reports are narrative texts with no means for storing, organizing, and aggregating the data across programs.

II. Current Action

The Corporation seeks approval of the Learn and Serve America Project Description Form. The form will ask Learn and Serve America grantees and their sub-grantees to : (1) Identify the frequency and types of student participants in service-learning programs; (2) identify the frequency and types of institutions and organizations sponsoring and collaborating with service-learning programs; (3) specify the types of services being provided to communities by students in service-learning; and (4) describe the local program operations and achievements. The information will be used to: (1) measure performance in terms set forth in the annual performance plan; (2) prepare descriptions of program activities and achievements with support from Learn and Serve America; (3) inform the Corporation, grantees, educational institutions, and the public concerning the nature, extent, and best practices in service-learning programs across the nation.

Type of Review: New approval.

Agency: Corporation for National and Community Service.

Title: Learn and Serve America Project Description Form.

OMB Number: None.

Agency Number: None.

Affected Public: Educators and other institutional personnel whose organizations receive grant funds from Learn and Serve America.

Total Respondents: 5,600 supervisors of Learn and Serve programs (70 percent response rate).

Frequency: Annually.

Average Time Per Response: 1 hour.

Estimated Total Burden Hours: 5,600 hours.

Total Burden Cost (capital/startup): $123,200 (5,600 respondents @ $22 each: $2 for copying, assembly, and mailing plus 1 hour per response @ $20/hour).

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: November 16, 1998.

Kenneth L. Klothen,

General Counsel.

[FR Doc. 98–31014 Filed 11–19–98; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board Task Force on Globalization and Security

ACTION: Notice of Advisory Committee Meetings.

SUMMARY: The Defense Science Board Task Force on Globalization and Security will meet in closed session on November 18–19, 1998 at Strategic Analysis Inc. (SAI), 4001 N. Fairfax Drive, Arlington, Virginia. In order for the Task Force to obtain time sensitive classified briefings, critical to the understanding of the issues, this meeting is scheduled on short notice.

The mission of the Defense Science Board is to advise the Secretary of Defense through the Under Secretary of Defense for Acquisition and Technology on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting the Task Force will develop advice to provide to the DepSecDef and USD(A&T) regarding transformations to the industrial base serving the DoD—assessing the significant benefits to the Department and the risks that our adversaries will be able to learn about our technology.

In accordance with Section 10(d) of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C. App. II, (1994)), it has been determined that this DSB Task Force meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1994), and that accordingly this meeting will be closed to the public.

Dated: November 13, 1998.

L.M. Bynum,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 98–30997 Filed 11–19–98; 8:45 am]

BILLING CODE 5000–04–M

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Deadline for Submission of Donation Applications for the Frigate Ex–KNOX (FF 1052)

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Department of the Navy hereby gives notice of the deadline of April 10, 1999 for submission of a donation application for the Frigate ex-KNOX (FF 1052), located at the Naval Inactive Ship Maintenance Facility, Bremerton, WA. A donation is anticipated pursuant to 10 U.S.C. Section 7306. Eligible recipients include: (1) Any State, Commonwealth, or possession of the United States or any municipal corporation or political subdivision thereof; (2) the District of Columbia; or (3) any not-for-profit or nonprofit entity. Transfer of a vessel under this law shall be made at no cost to the United States Government. The transferee will be required to maintain the vessel in a condition satisfactory to the Secretary of the Navy as a static museum/memorial. Prospective transferees must submit a comprehensive application addressing their plans for managing the significant financial, technical, environmental and curatorial responsibilities that accompany ships donated under this program.

DATES: Application deadline is April 10, 1999.

ADDRESSES: Applications should be sent to Program Executive Office for Expeditionary Warfare (PEO EXW), RMS334, Navy Donation Program Office, Naval Sea Systems Command, 2351 Jefferson Davis Highway, Arlington, VA 22242–5160.

FOR FURTHER INFORMATION CONTACT: Ms. Gloria Carvalho, Program Executive Office for Expeditionary Warfare (PEO EXW), PMS334, Navy Donation Program Office, Naval Sea Systems Command, 2531 Jefferson Davis Highway, Arlington, VA 22242–5160, telephone number (703) 602–5450.

Authority: 10 U.S.C. 7306.

Dated: November 12, 1998.

Ralph W. Corey,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 98–31056 Filed 11–19–98; 8:45 am]

BILLING CODE 3810–FF–M

DEPARTMENT OF DEFENSE

Department of the Navy

Plastic Processor Installations on Navy Ships

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: In accordance with the Act to Prevent Pollution from Ships, 33 U.S.C. 1902(e)(4)(B), the Secretary of Defense must report, beginning October 1, 1996, and each year until October 1, 1998, a list of the names of ships equipped with plastic processors. This notice is the third and final annual report.

FOR FURTHER INFORMATION CONTACT: Mr. Louis Maiuri, Office of the Chief of Naval Operations Environmental Protection, Safety and Occupational Health Division, Crystal Plaza #5, Room 654, 2211 South Clark Place, Arlington, Virginia, 22244–5108; 703–602–2602.

SUPPLEMENTARY INFORMATION: The International Maritime Convention on the Prevention of Pollution from Ships (MARPOL), as amended by the MARPOL Protocol of 1978, protects the ocean environment by prohibiting some discharges altogether, restricting other discharges to particular distances from land, and establishing ''special areas'' within which additional discharge limitations apply. One of the discharges specified for restriction under MARPOL Annex V is plastics.

The Act to Prevent Pollution from Ships, 33 U.S.C. 1902(e)(2), requires Navy ships equipped with plastics processors to comply with MARPOL Annex V provisions for the disposal of plastics. The law also establishes an installation schedule for plastic processor equipment aboard Navy ships. The first production unit was required to be installed by July 1, 1996, onboard a ship owned or operated by the Navy. At least 25 percent of Navy ships requiring processors were to be equipped by March 1, 1997. At least 50 percent of ships requiring processors were to be equipped by July 1, 1997. No less than 75 percent of ships requiring processors were to be equipped by July 1, 1998, and all vessels requiring plastics processors shall be equipped by December 31, 1998. The statute further requires the Secretary of Defense to report in the **Federal Register** the list of

the names of Navy ships equipped with plastic processors.

This **Federal Register** notice is the third and final required annual report. On October 1, 1998, 177 ships had been equipped with plastic processors. Plastic processors have now been installed on 94 percent of those ships requiring this equipment. Completion of plastic processor installations on 100 percent of Navy ships requiring this equipment will be completed by December 31, 1998. The list of 177 Navy ships equipped with plastic processors as of October 1, 1998 follows.

AGF	0011	CORONADO
AO ...	0178	MONONGAHELA
AO ...	0180	WILLIAMETTE
AOE	0001	SACRAMENTO
AOE	0002	CAMDEN
AOE	0003	SEATTLE
AOE	0004	DETROIT
AOE	0006	SUPPLY
AOE	0007	RAINIER
AOE	0008	ARCTIC
ARS ..	0050	SAFEGUARD
ARS ..	0051	GRASP
ARS ..	0052	SALVOR
ARS ..	0053	GRAPPLE
AS	0039	EMORY S LAND
AS	0040	FRANK CABLE
CG	0047	TICONDEROGA
CG	0049	VINCENNES
CG	0050	VALLEY FORGE
CG	0051	THOMAS S GATES
CG	0052	BUNKER HILL
CG	0053	MOBILE BAY
CG	0054	ANTIETAM
CG	0055	LEYTE GULF
CG	0056	SAN JACINTO
CG	0057	LAKE CHAMPLAIN
CG	0058	PHILIPPINE SEA
CG	0059	PRINCETON
CG	0060	NORMANDY
CG	0061	MONTEREY
CG	0062	CHANCELLORSVILLE
CG	0063	COWPENS
CG	0064	GETTYSBURG
CG	0065	CHOSIN
CG	0067	SHILOH
CG	0068	ANZIO
CG	0070	LAKE ERIE
CG	0071	CAPE ST GEORGE
CG	0072	VELLA GULF
CG	0073	PORT ROYAL
CGN	0037	SOUTH CAROLINA
CV	0063	KITTY HAWK
CV	0064	CONSTELLATION
CV	0067	JOHN F KENNEDY
CVN	0065	ENTERPRISE
CVN	0069	DWIGHT D EISENHOWER
CVN	0070	CARL VINSON
CVN	0071	THEODORE ROOSEVELT
CVN	0072	ABRAHAM LINCOLN
CVN	0074	JOHN C STENNIS
CVN	0075	HARRY S TRUMAN
DD	0963	SPRUANCE
DD	0964	PAUL F FOSTER
DD	0965	KINKAID
DD	0966	HEWIT
DD	0967	ELLIOT
DD	0968	ARTHUR W RADFORD
DD	0960	PETERSON
DD	0970	CARON
DD	0971	DAVID R RAY
DD	0972	OLDENDORF
DD	0973	JOHN YOUNG
DD	0975	O'BRIEN
DD	0977	BRISCOE
DD	0978	STUMP
DD	0979	CONOLLY
DD	0980	MOOSEBRUGGER
DD	0981	JOHN HANCOCK
DD	0982	NICHOLSON
DD	0983	JOHN RODGERS
DD	0987	O'BANNON
DD	0988	THORN
DD	0989	DEYO
DD	0990	INGERSOLL
DD	0991	FIFE
DD	0992	FLETCHER
DD	0997	HAYLER
DDG	0051	ARLEIGH BURKE
DDG	0052	JOHN BARRY
DDG	0053	JOHN PAUL JONES
DDG	0054	CURTIS WILBUR
DDG	0055	STOUT
DDG	0056	JOHN S MCCAIN
DDG	0057	MITSCHER
DDG	0058	LABOON
DDG	0059	RUSSELL
DDG	0060	PAUL HAMILTON
DDG	0061	RAMAGE
DDG	0062	FITZGERALD
DDG	0063	STETHEM
DDG	0064	CARNEY
DDG	0065	BENFOLD
DDG	0066	GONZALEZ
DDG	0067	COLE
DDG	0068	THE SULLIVANS
DDG	0069	MILIUS
DDG	0070	HOPPER
DDG	0071	ROSS
DDG	0072	MAHAN
DDG	0073	DECATUR
DDG	0074	MCFAUL
DDG	0075	DONALD COOK
DDG	0994	CALLAGHAN
DDG	0995	SCOTT
DDG	0996	CHANDLER
FFG ..	0008	MCINERNEY
FFG ..	0009	WADSWORTH
FFG ..	0012	GEORGE PHILIP
FFG ..	0014	SIDES
FFG ..	0015	ESTOCIN
FFG ..	0029	STEPHEN W GROVES
FFG ..	0032	JOHN L HALL
FFG ..	0033	JARRETT
FFG ..	0036	UNDERWOOD
FFG ..	0037	CROMMELIN
FFG ..	0038	CURTS
FFG ..	0039	DOYLE
FFG ..	0040	HALYBURTON
FFG ..	0041	MCCLUSKY
FFG ..	0042	KLAKRING
FFG ..	0043	THACH
FFG ..	0045	DEWERT
FFG ..	0056	RENTZ
FFG ..	0047	NICHOLAS
FFG ..	0048	VANDEGRIFT
FFG ..	0049	ROBERT G BRADLEY
FFG ..	0050	TAYLOR
FFG ..	0051	GARY
FFG ..	0052	CARR
FFG ..	0053	HAWES
FFG ..	0054	FORD
FFG ..	0055	ELROD
FFG ..	0056	SIMPSON
FFG ..	0057	REUBEN JAMES
FFG ..	0058	SAMUEL B ROBERTS
FFG ..	0059	KAUFFMAN
FFG ..	0060	RODNEY M DAVIS
FFG ..	0061	INGRAHAM
LCC ..	0019	BLUE RIDGE
LCC ..	0020	MOUNT WHITNEY
LHA	0001	TARAWA
LHA	0002	SAIPAN
LHA	0003	BELLEAU WOOD
LHA	0004	NASSAU
LHA	0005	PELELIU
LHD	0001	WASP
LHD	0002	ESSEX
LHD	0003	KEARSARGE
LHD	0004	BOXER
LHD	0005	BATAAN
LHD	0006	BONHOMME RICHARD
LPD ..	0004	AUSTIN
LPD ..	0005	OGDEN
LPD ..	0006	DULUTH
LPD ..	0007	CLEVELAND
LPD ..	0008	DUBUQUE
LPD ..	0009	DENVER
LPD ..	0010	JUNEAU
LPD ..	0012	SHEVEPORT
LPD ..	0013	NASHVILLE
LPD ..	0014	TRENTON
LPD ..	0015	PONCE
LSD ..	0036	ANCHORAGE
LSD ..	0037	PORTLAND
LSD ..	0039	MOUNT VERNON
LSD ..	0041	WHIDBEY ISLAND
LSD ..	0042	GERMANTOWN
LSD ..	0043	FORT MCHENRY
LSD ..	0044	GUNSTON HALL
LSD ..	0045	COMSTOCK
LSD ..	0046	TORTUGA
LSD ..	0047	RUSHMORE
LSD ..	0048	ASHLAND
LSD ..	0049	HARPERS FERRY
LSD ..	0050	CARTER HALL
LSD ..	0051	OAK HILL
MCS	0012	INCHON

Dated: November 10, 1998.

Ralph W. Corey,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 98–31054 Filed 11–19–98; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Garbage Discharges for Navy Ships Into the International Maritime Convention for the Prevention of Pollution From Ships (MARPOL) Annex V Special Areas

AGENCY: Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The Secretary of Defense must report annually on the amount and nature of garbage discharges from Navy ships operating in special areas, when such discharges are not otherwise authorized under the Act to Prevent Pollution from Ships (APPS), 33 U.S.C. 1901, *et seq.* This notice is the fifth annual report.

FOR FURTHER INFORMATION CONTACT: Mr. Louis Maiuri, Office of the Chief of Naval Operations Environmental Protection, Safety and Occupational Health Division, Crystal Plaza #5, Room 654, 2211 South Clark Place, Arlington, Virginia, 22244–5108; 703–602–2602.

SUPPLEMENTARY INFORMATION: The International Maritime Convention on the Prevention of Pollution from ships (MARPOL) as amended by the MARPOL Protocol of 1978, protects the ocean environment by prohibiting some discharges altogether, restricting other discharges to particular distances from land, and establishing ''special areas'' within which additional discharge limitations apply. Special areas are particular bodies of water, which, because of their oceanographic characteristics and ecological significance, require protective measures more strict than other areas of the ocean. Within special areas that are in effect internationally, except under emergency circumstances, the only authorized garbage discharge from vessels is food waste. At present, three special areas are in effect: the North Sea, the Baltic Sea, and the Antarctic Region.

The Act to Prevent Pollution from Ships established deadlines for compliance by U.S. Navy ships with the Annex V special area requirements. Surface ships must comply with the special area requirements by December 31, 2000. Submarines must comply with the special area requirements by December 31, 2008. APPS further requires the Secretary of Defense to report in the **Federal Register** the amount and nature of Navy ship discharges in special areas, not otherwise authorized under MARPOL Annex V.

This **Federal Register** notice is the fifth of the required annual reports. This report covers the period between August 1, 1997, and September 30, 1998. During the period August 1, 1997, through September 30, 1998, there were no garbage discharges from Navy ships into MARPOL Annex V special areas that were not authorized under MARPOL Annex V.

Dated: November 9, 1998.

Ralph W. Corey,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 98–31055 Filed 11–19–98; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF EDUCATION

Notice of Proposed Information Collection Requests

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Group, Office of the Chief Financial and Chief Information Officer, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before January 19, 1999.

ADDRESSES: Written comments and requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the internet address Pat__Sherrill@ed.gov, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Information Management Group, Office of the Chief Financial and Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g. new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: November 16, 1998.

Kent H. Hannaman,

Leader, Information Management Group, Office of the Chief Financial and Chief Information Officer.

Office of Educational Research and Improvement

Type of Review: New.
Title: National Study of Charter Schools.
Frequency: Annually.
Affected Public: Not-for-profit institutions; State, local or Tribal Gov't, SEAs or LEAs.
Reporting and Recordkeeping Hour Burden: Responses: 1,113; Burden Hours: 509.
Abstract: This four-year study of charter schools will examine the impact of charter schools on student achievement, on education reform, and on an array of other issues. The study includes an annual survey of the universe of charter schools and site visits at a sample of charter schools and comparison schools.

[FR Doc. 98–31015 Filed 11–19–98; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Submission for OMB Review; Comment Request

AGENCY: Department of Education.

SUMMARY: The Leader, Information Management Group, Office of the Chief Financial and Chief Information Officer, invites comments on the submission for OMB review as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments on or before December 21, 1998.

ADDRESSES: Written comments should be addressed to the Office of Information and Regulatory Affairs, Attention: Danny Werfel, Desk Officer,

Department of Education, Office of Management and Budget, 725 17th Street, NW., Room 10235, New Executive Office Building, Washington, DC 20503 or should be electronically mailed to the internet address *Werfel__d@al.eop.gov*. Requests for copies of the proposed information collection requests should be addressed to Patrick J. Sherrill, Department of Education, 600 Independence Avenue, S.W., Room 5624, Regional Office Building 3, Washington, D.C. 20202–4651, or should be electronically mailed to the internet address *Pat__Sherrill@ed.gov*, or should be faxed to 202–708–9346.

FOR FURTHER INFORMATION CONTACT: Patrick J. Sherrill (202) 708–8196. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Leader, Information Management Group, Office of the Chief Financial and Chief Information Officer, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection, grouped by office, contains the following: (1) Type of review requested, e.g., new, revision, extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Recordkeeping burden. OMB invites public comment at the address specified above. Copies of the requests are available from Patrick J. Sherrill at the address specified above.

Dated: November 16, 1998.

Kent H. Hannaman,

Leader, Information Management Group, Office of the Chief Financial and Chief Information Officer.

Office of Postsecondary Education

Type of Review: Revision.

Title: Federal Family Education Loan Program and William D. Ford Federal Direct Loan Program, Loan Discharge Applications.

Frequency: One time.

Affected Public: Individuals or households.

Reporting and Recordkeeping Hour Burden: Responses: 70,000; Burden Hours: 30,500.

Abstract: These forms will serve as the means of collecting the information necessary to determine whether a FFEL or Direct Loan Borrower qualifies for a loan discharge based on total and permanent disability, school closure, false certification of student eligibility, or unauthorized signature.

Office of Postsecondary Education

Type of Review: Revision.

Title: Federal Direct Consolidation Loan Program Application Documents.

Frequency: On occasion.

Affected Public: Individuals or households; Businesses or other for-profits.

Reporting and Recordkeeping Hour Burden: Responses: 707,000; Burden Hours: 528,250.

Abstract: These forms are the means by which a borrower applies for/promises to repay a Federal Direct Consolidation Loan and a lender verifies an eligible loan to be consolidated.

[FR Doc. 98–31016 Filed 11–19–98; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Hydrogen Technical Advisory Panel

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Public Law No. 92–463, 86 Stat. 770, as amended), notice is hereby given of the following advisory committee meeting: Hydrogen Technical Advisory Panel.

Date: Tuesday, December 8, 1998, 9:00 A.M.–5:00 P.M., Wednesday, December 9, 1998, 9:00 A.M.–3:30 P.M.

Place: Florida Solar Energy Center, 1679 Clearlake Road, Cocoa, Florida 32922–5703; Telephone: 407–638–1000.

FOR FURTHER INFORMATION CONTACT: Russell Eaton, Designated Federal Officer, Department of Energy, Golden Field Office, 1617 Cole Blvd., Golden, CO 80401, Telephone: 303–275–4740.

SUPPLEMENTARY INFORMATION:

Purpose of the Panel: The Hydrogen Technical Advisory Panel (HTAP) will advise the Secretary of Energy who has the overall management responsibility for carrying out the programs under the Matsunaga Hydrogen Research, Development, and Demonstration Program Act of 1990, Public Law No. 101–566 and the Hydrogen Future Act of 1996, Public Law No. 104–271. The Panel will review and make any necessary recommendations to the Secretary on the following items: (1) The implementation and conduct of programs required by the Act, and (2) the economic, technological, and environmental consequences of the deployment of hydrogen production and use systems.

Tentative Schedule

Tuesday, November 3, 1998

9:00 A.M. Opening Comments—D. Nahmias
9:15 Introduction of Panelists and Remarks—D. Nahmias/R. Eaton
9:45 DOE Hydrogen Program Report—S. Gronich/N. Rossmeissl
10:00 DOE Hydrogen Program Budget, FY 1999—S. Gronich
10:30 Break
10:45 DOE Report to Congress—S. Gronich
12:00 P.M. Lunch
1:30 HTAP Report to Congress (This will include a signing ceremony by the HTAP members)—D. Nahmias
2:45 IEA Report-International Coordination—N. Rossmeissl
3:00 Break
3:30 Public Comments—Audience
4:00 HTAP Panel Comments—Panel
5:00 Adjourn
6:00 Reception

Wednesday, November 4, 1998

9:00 AM Round Table Discussion on Coordination and Collaboration (DOE Offices of Fossil Energy, Energy Research, Transportation Technologies, Biofuels; DOT and NASA)— Panel/Agency Representatives
12:00 PM Lunch
1:45 Public Comments—Audience
3:15 HTAP Discussion, Comments and Roundup—Panel
3:30 Adjourn

Public Participation: The meeting is open to the public. Written statements may be filed with the Committee either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should contact Russell Eaton's office at the address or telephone number listed above. Requests must be received 5 days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. The Designated Federal Official is

empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Each individual wishing to make public comment will be provided a maximum of 5 minutes to present their comments.

Minutes: The minutes of this meeting will be available for public review and copying at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC 20585 between 9 A.M. and 4 P.M., Monday–Friday, except Federal holidays. Minutes will also be available by writing to Russell Eaton, Department of Energy, Golden Field Office, 1617 Cole Blvd.,Golden, CO 80401, or by calling (303) 275–4740.

Issued at Washington, DC, on November 17, 1998.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 98–31059 Filed 11–19–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Secretary of Energy Advisory Board; Notice of Open Meeting

AGENCY: Department of Energy.

SUMMARY: Consistent with the provisions of the Federal Advisory Committee Act (Public Law 92–463, 86 Stat. 770), notice is hereby given of the following advisory committee meeting:

Name: Secretary of Energy Advisory Board—Laboratory Operations Board.

Date and Time: Monday, December 7, 1998, 1:00 P.M.–4:30 P.M.

Place: Lawrence Livermore National Laboratory (LLNL), I–580 Exit Vasco Road, Building 170, Conference Room 1091, Livermore. California.

Note: Public attendees are requested to enter through the West Gate Badging Office.

FOR FURTHER INFORMATION CONTACT: Richard C. Burrow, Secretary of Energy Advisory Board (AB–1), US Department of Energy, 1000 Independence Avenue, SW, Washington, D.C. 20585, (202) 586–1709.

SUPPLEMENTARY INFORMATION: The purpose of the Laboratory Operations Board is to provide advice to the Secretary of Energy Advisory Board regarding the strategic direction of the Department's laboratories, the coordination of budget and policy issues affecting laboratory operations, and the reduction of unnecessary and counterproductive management burdens on the laboratories. The Laboratory Operations Board's goal is to facilitate the productive and cost-effective utilization of the Department's laboratory system and the application of best business practices.

Tentative Agenda:

Monday, December 7, 1998

1:00–1:30 P.M. Co-Chairs' Opening Remarks
1:30–2:00 P.M. Status Reports on Outstanding Actions
2:00–3:00 P.M. Discussion of Laboratory Profile Report Submissions
3:00–4:15 P.M. Background Presentations on Departmental Organization and Governance
4:15–4:30 P.M. Public Comment Period
4:30 P.M. Adjourn

This tentative agenda is subject to change. A final agenda will be available at the meeting.

Public Participation: The Chairman of the Laboratory Operations Board is empowered to conduct the meeting in a way which will, in the Chairman's judgment, facilitate the orderly conduct of business. During its meeting in Livermore, California, the Laboratory Operations Board welcomes public comment. Members of the public will be heard in the order in which they sign up at the beginning of the meeting. The Laboratory Operations Board will make every effort to hear the views of all interested parties. Written comments may be submitted to Skila Harris, Executive Director, Secretary of Energy Advisory Board, AB–1, US Department of Energy, 1000 Independence Avenue, SW, Washington, DC 20585.

Minutes: Minutes and a transcript of the meeting will be available for public review and copying approximately 30 days following the meeting at the Freedom of Information Public Reading Room, 1E–190 Forrestal Building, 1000 Independence Avenue, SW, Washington, D.C., between 9:00 A.M. and 4:00 P.M., Monday through Friday except Federal holidays. Information on the Laboratory Operations Board may also be found at the Secretary of Energy Advisory Board's web site, located at http://www.hr.doe.gov/seab.

Issued at Washington, D.C., on November 17, 1998.

Rachel M. Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 98–31060 Filed 11–19–98; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Application Filed With the Commission

November 16, 1998.

Take notice that the following hydroelectric application has been filed with the Federal Energy Regulatory Commission and is available for public inspection.

a. *Type of Application:* Amendment of Exemption.

b. *Project No:* 2869–007.

c. *Date Filed:* 06/22/98.

d. *Applicant:* Village of Potsdam, New York.

e. *Name of Project:* Potsdam Water Power Project.

f. *Location:* On the Raquette River in St. Lawrence County, New York.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. § 791(a)–825(r).

h. *Applicant Contact:* Frank O. Christie, Christie Engineering, 8 East Main St., Malone, NY 12953, (518) 483–1945.

i. *FERC Contact:* Mohamad Fayyad, (202) 219–2665.

j. *Comment Date:* December 21, 1998.

k. *Description of Amendment:* The exemptee is proposing to add a new powerhouse at the site. The existing project consists of the East Dam and West Dam separated by an island, a 300-acre reservoir, and an 800–kW powerhouse at the East Dam. The proposed powerhouse would consist of an intake and powerhouse at the West Dam with a capacity of 700 kW.

Initially, on February 27, 1997, the exemptee filed a new license application for the above proposal of the 700–kW powerhouse under docket No. P–11289. The proposal in the license application did not include the existing exempted project. We informed the exemptee that its proposal and its existing exempted project would constitute a complete unit of development; one project. On June 22, 1998, the exemptee decided to file this amendment application.

1. This notice also consists of the following standard paragraphs: B, C1, and D2.

B. Comments, Protests, or Motions to Intervene—Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR Sections 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those

who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

C1. Filing and Service of Responsive Documents—Any filings must bear in all capital letters the title ''COMMENTS,'' ''RECOMMENDATIONS FOR TERMS AND CONDITIONS,'' ''PROTEST'' OR ''MOTION TO INTERVENE,'' as applicable, and the project number of the particular application to which the filing is in response. Any of these documents must be filed by providing the original and 8 copies to: The Secretary, Federal Energy Regulatory Commission, 888 First Street, N.E., Washington, DC 20426. Motions to intervene must also be served upon each representative of the applicant specified in the particular application.

D2. Agency Comments—The Commission invites federal, state, and local agencies to file comments on the described application. (Agencies may obtain a copy of the application directly from the applicant. The application may be viewed on the web site at www.ferc.fed.us. Call (202) 208–2222 for assistance.) If an agency does not file comments within the time specified for filing comments, the Commission will presume that the agency has none. One copy of an agency's comments must also be sent to the applicant's representatives.

David P. Boergers,

Secretary.

[FR Doc. 98–31029 Filed 11–19–98; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice

Novemeber 17, 1998.

The following notice of meeting is published pursuant to section 3(a) of the Government in the Sunshine Act (Pub. L. No. 94–409), 5 U.S.C. 552b:

AGENCY HOLDING MEETING: Federal Energy Regulatory Commission.

DATE AND TIME: November 24, 1998, 10:00 a.m.

PLACE: Room 2C, 888 first Street, N.E., Washington, D.C. 20426.

STATUS: Open.

MATTERS TO BE CONSIDERED: Agenda.

Note.—Items listed on the agenda may be deleted without further notice.

CONTACT PERSON FOR MORE INFORMATION: David P. Boergers, Secretary, Telephone (202) 208–0400, for a recording listing items stricken from or added to the meeting, call (202) 208–1627.

This is a list of matters to be considered by the Commission. It does not include a listing of all papers relevant to the items on the agenda; however, all public documents may be examined in the reference and information center.

Consent Agenda—Hydro 709th Meeting—November 24, 1998; Regular Meeting (10:00 a.m.)

CAH–1.
DOCKET# P–618,080, ALABAMA POWER COMPANY
CAH–2.
DOCKET# P–1862,017, CITY OF TACOMA, WASHINGTON
CAH–3.
DOCKET# P–2458,028, GREAT NORTHERN PAPER, INC.
OTHER#S P–2572,012, GREAT NORTHERN PAPER, INC.
CAH–4.
DOCKET# P–2696,006, NIAGARA MOHAWK POWER CORPORATION
CAH–5.
DOCKET# P–2016,029, CITY OF TACOMA, WASHINGTON
CAH–6.
DOCKET# P–2916,004, EAST BAY MUNICIPAL UTILITY DISTRICT

Consent Agenda—Electric

CAE–1.
DOCKET# ER99–28,000, SIERRA PACIFIC POWER COMPANY
CAE–2.
DOCKET# ER99–233,000, MONTAUP ELECTRIC COMPANY
CAE–3.
DOCKET# ER99–25,000, PECO ENERGY COMPANY
CAE–4.
DOCKET# ER98–4512,000, CONSOLIDATED WATER POWER COMPANY
CAE–5.
DOCKET# ER99–51,000, COMMONWEALTH EDISON COMPANY
CAE–6.
DOCKET# ER99–14,000, SELECT ENERGY, INC.
CAE–7.
DOCKET# EC96–19,028, CALIFORNIA POWER EXCHANGE CORPORATION
OTHER#S EC96–19,029, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
EL98–51,000, ERIC C. WOYCHIK, ET AL. V. CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION AND CALIFORNIA ELECTRICITY OVERSIGHT BOARD
ER96–1663,029, CALIFORNIA POWER EXCHANGE CORPORATION
ER96–1663,030, CALIFORNIA INDEPENDENT SYSTEM OPERATOR CORPORATION
CAE–8.
DOCKET# ER95–854,000, KENTUCKY UTILITIES COMPANY
CAE–9.
DOCKET# EF98–5031,000, UNITED STATES DEPARTMENT OF ENERGY—WESTERN AREA POWER ADMINISTRATION
CAE–10.
DOCKET# EC98–45,000, CENTRAL MAINE POWER COMPANY, THE UNION WATER-POWER COMPANY, AND CUMBERLAND SECURITIES CORPORATION, ET AL.
OTHER#S ER98–3507,000, CENTRAL MAINE POWER COMPANY, THE UNION WATER-POWER COMPANY, AND CUMBERLAND SECURITIES CORPORATION, ET AL.
CAE–11.
DOCKET# OA97–573,000, ATLANTIC CITY ELECTRIC COMPANY
OTHER#S EL98–27,000, DELMARVA POWER & LIGHT COMPANY
ER97–3189,010, ATLANTIC CITY ELECTRIC COMPANY
OA97–586,000, DELMARVA POWER & LIGHT COMPANY
CAE–12.
DOCKET# EC98–54,000, ROCHESTER GAS AND ELECTRIC CORPORATION
CAE–13.
DOCKET# ER96–58,000, ALLEGHENY POWER SERVICE CORPORATION
CAE–14.
DOCKET# ER95–530,000, OCEAN STATE POWER II
OTHER#S ER95–533,000, OCEAN STATE POWER
ER97–1890,000, OCEAN STATE POWER II
ER97–1899,000, OCEAN STATE POWER
ER98–1717,000, OCEAN STATE POWER
ER98–1718,000, OCEAN STATE POWER II
CAE–15.
DOCKET# EL96–43,000, NEW HAMPSHIRE ELECTRIC COOPERATIVE V. PUBLIC SERVICE COMPANY OF NEW HAMPSHIRE
OTHER#S EL97–33,000, NEW HAMPSHIRE ELECTRIC COOPERATIVE V. PUBLIC SERVICE COMPANY OF NEW HAMPSHIRE
CAE–16.
DOCKET# ER98–2537,000, LONG BEACH GENERATION LLC
CAE–17.
DOCKET# QF95–197,001, TWO ELK GENERATION PARTNERS, LIMITED PARTNERSHIP
CAE–18.
DOCKET# ER96–222,000, SOUTHERN CALIFORNIA EDISON COMPANY
OTHER#S OA96–76,000, SOUTHERN CALIFORNIA EDISON COMPANY
OA97–602,000, SOUTHERN CALIFORNIA EDISON COMPANY
OA97–604,000, SOUTHERN CALIFORNIA EDISON COMPANY
CAE–19.
DOCKET# ER98–1438,001, MIDWEST INDEPENDENT TRANSMISSION SYSTEM OPERATOR, INC.
OTHER#S EC98–24,001, THE CINCINNATI GAS & ELECTRIC COMPANY, COMMONWEALTH EDISON COMPANY AND COMMONWEALTH EDISON COMPANY OF INDIANA, ET AL.
CAE–20.

DOCKET# ER98–3681,001, FIRSTENERGY TRADING & POWER MARKETING, INC.
CAE–21.
DOCKET# EL98–26,001, TRANSMISSION AGENCY OF NORTHERN CALIFORNIA V. PACIFIC GAS & ELECTRIC COMPANY
CAE–22.
DOCKET# RM93–24,001, REVISION OF FUEL COST ADJUSTMENT CLAUSE REGULATION RELATING TO FUEL PURCHASES FROM COMPANY-OWNED OR CONTROLLED SOURCE
CAE–23.
DOCKET# ER96–58,001, ALLEGHENY POWER SERVICE CORPORATION
CAE–24.
DOCKET# EL96–65,001, PENNSYLVANIA POWER & LIGHT COMPANY V. SCHUYLKILL ENERGY RESOURCES, INC.
OTHER#S QF85–720,006, PENNSYLVANIA POWER & LIGHT COMPANY V. SCHUYLKILL ENERGY RESOURCES, INC.
CAE–25.
DOCKET# EL98–72,000, CLARKSDALE PUBLIC UTILITIES COMMISSION V. ENTERGY SERVICES, INC.
OTHER#S EL98–73,000, CLARKSDALE PUBLIC UTILITIES COMMISSION V. ENTERGY SERVICES, INC.
ER99–218,000, ENTERGY SERVICES, INC.
CAE–26.
DOCKET# EL95–24,000, GOLDEN SPREAD ELECTRIC COOPERATIVE, INC. V. SOUTHWESTERN PUBLIC SERVICE COMPANY
CAE–27.
DOCKET# EL95–37,000, NEW HAMPSHIRE ELECTRIC COOPERATIVE, INC. V. PUBLIC SERVICE COMPANY OF NEW HAMPSHIRE
OTHER#S EL98–35,000, NEW HAMPSHIRE ELECTRIC COOPERATIVE, INC. V. PUBLIC SERVICE COMPANY OF NEW HAMPSHIRE
CAE–28.
OMITTED
CAE–29.
DOCKET# RM99–2,000, REGIONAL TRANSMISSION ORGANIZATIONS
CAE–30.
DOCKET# NJ97–9,003, COLORADO SPRINGS UTILITIES
OTHER#S NJ97–2,003, OMAHA PUBLIC POWER DISTRICT
NJ97–8,002, SOUTH CAROLINA PUBLIC SERVICE AUTHORITY
NJ97–10,001, NEW YORK POWER AUTHORITY
NJ97–13,002, ORLANDO UTILITIES COMMISSION
NJ97–14,001, EAST KENTUCKY POWER COOPERATIVE, INC.
CAE–31.
DOCKET# ER99–54,000, BOSTON EDISON COMPANY

CONSENT AGENDA—GAS AND OIL

CAG–1.
DOCKET# GT99–4,000, TENNESSEE GAS PIPELINE COMPANY
CAG–2.
DOCKET# RP99–92,000, TEXAS EASTERN TRANSMISSION CORPORATION
OTHER#S RP99–92,001, TEXAS EASTERN TRANSMISSION CORPORATION
CAG–3.
DOCKET# RP99–93,000, TEXAS EASTERN TRANSMISSION CORPORATION
OTHER#S RP99–93,001, TEXAS EASTERN TRANSMISSION CORPORATION
CAG–4.
DOCKET# RP99–108,000, MIDWESTERN GAS TRANSMISSION COMPANY
CAG–5.
DOCKET# RP99–109,000, EAST TENNESSEE NATURAL GAS COMPANY
CAG–6.
DOCKET# RP99–110,000, EAST TENNESSEE NATURAL GAS COMPANY
CAG–7.
DOCKET# RP99–114,000, COLUMBIA GAS TRANSMISSION CORPORATION
CAG–8.
DOCKET# TM99–1–20,000, ALGONQUIN GAS TRANSMISSION COMPANY
CAG–9.
DOCKET# SA98–21,000, SALLY L. BONE
CAG–10.
DOCKET# SA98–18,000, RIVIERA DRILLING & EXPLORATION COMPANY
CAG–11.
DOCKET# SA98–62,000, NED E. AND DOROTHY J. LOWRY
CAG–12.
DOCKET# SA98–79,000, RUTH LAWHORN
CAG–13.
DOCKET# GP98–24,000, BILL C. ROMIG
CAG–14.
DOCKET# RP99–96,000, KERN RIVER GAS TRANSMISSION COMPANY
CAG–15.
DOCKET# RP99–98,000, WILLISTON BASIN INTERSTATE PIPELINE COMPANY
CAG–16.
DOCKET# RP99–99,000, NORTHERN NATURAL GAS COMPANY
CAG–17.
OMITTED
CAG–18.
DOCKET# RP99–107,000, PANHANDLE EASTERN PIPE LINE COMPANY
CAG–19.
DOCKET# RP99–111,000, KOCH GATEWAY PIPELINE COMPANY
CAG–20.
DOCKET# TM98–2–59,003, NORTHERN NATURAL GAS COMPANY
CAG–21.
OMITTED
CAG–22.
OMITTED
CAG–23.
DOCKET# PR98–12,000, ENOGEX, INC.
OTHER#S PR98–12,001, ENOGEX, INC.
CAG–24.
DOCKET# RP97–406,018, CNG TRANSMISSION CORPORATION ET AL.
OTHER#S CP98–754,000, CNG TRANSMISSION CORPORATION
CAG–25.
DOCKET# RP98–99,005, TENNESSEE GAS PIPELINE COMPANY
CAG–26.
DOCKET# RP97–346,017, EQUITRANS, L.P.
OTHER#S RP98–123,004, EQUITRANS, L.P.
TM97–3–24,005, EQUITRANS, L.P.
CAG–27.
OMITTED
CAG–28.
DOCKET# RP97–469,005, NATURAL GAS PIPELINE COMPANY OF AMERICA
CAG–29.
DOCKET# RP98–25,005, WEST TEXAS GAS, INC.
OTHER#S RP98–25,006, WEST TEXAS GAS, INC.
CAG–30.
OMITTED
CAG–31.
DOCKET# RP99–26,000, NORTHWEST PIPELINE CORPORATION
CAG–32.
DOCKET# RP95–136,000, WILLIAMS GAS PIPELINES CENTRAL, INC.
CAG–33.
DOCKET# RP96–190,013, COLORADO INTERSTATE GAS COMPANY
CAG–34.
DOCKET# RP98–293,002, WILLIAMS GAS PIPELINES CENTRAL, INC
CAG–35.
DOCKET# RP97–373,015, KOCH GATEWAY PIPELINE COMPANY
CAG–36.
DOCKET# RP95–197,033, TRANSCONTINENTAL GAS PIPE LINE CORPORATION
CAG–37.
DOCKET# GP97–6,001, PLAINS PETROLEUM COMPANY AND PLAINS PETROLEUM OPERATING COMPANY
OTHER#S GP98–25,001, PLAINS PETROLEUM COMPANY AND PLAINS PETROLEUM OPERATING COMPANY
CAG–38.
DOCKET# RP98–54,015, COLORADO INTERSTATE GAS COMPANY
OTHER#S GP98–1,002, UNION PACIFIC RESOURCES COMPANY
GP98–10,002, AMOCO PRODUCTION COMPANY
GP98–11,002, OXY USA, INC.
GP98–17,002, ANADARKO PETROLEUM CORPORATION
CAG–39.
DOCKET# RP98–362,001, NATURAL GAS PIPELINE COMPANY OF AMERICA
CAG–40.
OMITTED
CAG–41.
OMITTED
CAG–42.
DOCKET# CP97–168,002, ALLIANCE PIPELINE L.P.
OTHER#S CP97–169,002, ALLIANCE PIPELINE L.P.
CP97–177,002, ALLIANCE PIPELINE L.P.
CP97–178,002, ALLIANCE PIPELINE L.P.
CAG–43.
DOCKET# CP97–667,001, EL PASO NATURAL GAS COMPANY
CAG–44.
DOCKET# CP97–691,001, SOUTHERN NATURAL GAS COMPANY
CAG–45.
OMITTED
CAG–46.

DOCKET# CP98–167,003, PG&E GAS TRANSMISSION, NORTHWEST CORPORATION
CAG–47.
DOCKET# CP98–266, 001, ENOGEX INTERSTATE TRANSMISSION, LLC AND OZARK GAS TRANSMISSION, L.L.C.
OTHER#S CP98–266, 002, OZARK GAS TRAMSMISSION, L.L.C.
CP98–266, 003, OZARK GAS TRANSMISSION, L.L.C.
CP98–266, 004, OZARK GAS TRANSMISSION, L.L.C.
CP98–267, 001, ENOGEX INTERSTATE TRANSMISSION, LLC AND OZARK GAS TRANSMISSION, L.L.C.
CP98–268, 001, ENOGEX INTERSTATE TRANSMISSION, LLC AND OZARK GAS TRANSMISSION, L.L.C.
CAG–48.
OMITTED
CAG–49.
OMITTED
CAG–50.
OMITTED
CAG–51.
DOCKET# CP97–237, 000, PANHANDLE EASTERN PIPE LINE COMPANY AND SOUTHWEST GAS STORAGE COMPANY
CAG–52.
DOCKET# CP98–590, 000, TEXAS EASTERN TRANSMISSION CORPORATION
CAG–53.
DOCKET# CP98–70, 000, THE UNION LIGHT, HEAT & POWER COMPANY
OTHER#S CP98–245, 000, COLUMBIA GAS TRANSMISSION CORPORATION
CAG–54.
DOCKET# CP98–103, 000, K N INTERSTATE GAS TRANSMISSION COMPANY
CAG–55.
DOCKET# CP98–522, 000, TEXAS GAS TRANSMISSION CORPORATION AND COLUMBIA GULF TRANSMISSION COMPANY
CAG–56.
DOCKET# CP98–767, 000, GREAT LAKES GAS TRANSMISSION, LIMITED PARTNERSHIP
CAG–57.
OMITTED
CAG–58.
OMITTED
CAG–59.
DOCKET# RP98–365, 000, SEA ROBIN PIPELINE COMPANY
OTHER#S RP98–365, 002, SEA ROBIN PIPELINE COMPANY
CAG–60.
DOCKET# OR98–11, 000, SFPP, L.P.
CAG–61.
DOCKET# RP99–113, 000, TENNESSEE GAS PIPELINE COMPANY
CAG–62.
DOCKET# RP99–118, 000, ANR PIPELINE COMPANY
CAG–63.
DOCKET# RP99–119, 000, EAST TENNESSEE NATURAL GAS COMPANY
CAG–64.
DOCKET# RP99–120, 000, MIDWESTERN GAS TRANSMISSION COMPANY
CAG–65.
DOCKET# RP99–126, 000, SOUTHERN NATURAL GAS COMPANY

Hydro Agenda

H–1.
RESERVED

Electric Agenda

E–1.
RESERVED

Oil and Gas Agenda

I. Pipeline Rate Matters

PR–1.
RESERVED

II. Pipeline Certificate Matters

PC–1.
RESERVED

David P. Boergers,

Secretary.

[FR Doc. 98–31100 Filed 11–17–98; 4:03 pm]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5497–2]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared November 2, 1998 through November 6, 1998 pursuant to the Environmental Review Process (ERP), under Section 309 of the Clean Air Act and Section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7167. An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in FR dated April 10, 1998 (62 FR 17856).

Draft EISs

ERP No. D–AFS–J61100–CO: Rating EO2, Arapahoe Basin Ski Area Master Development Plan, Construction and Operation, COE Section 404 Permit, White River National Forest, Dillon Ranger District, Summit County, CO.

Summary: EPA expressed environmental objections based on the projects potential adverse impacts to wetlands, water quality and quantity, as well as aquatic resources.

ERP No. D–AFS–J65287–SD: Rating EC2, Veteran/Boulder Area Project, Enhancement of Vegetative Diversity, Improve Forest Health and to Improve Wildlife Habitats, Implementation, Black Hills National Forest, Spearfish and Nemo Ranger District, Lawrence and Meade Counties, SD.

Summary: EPA expressed environmental concerns of the project on existing 303(d) listed waters.

ERP No. D–AFS–L65308–ID: Rating EC2, Eagle Bird Project Area, Timber Harvesting and Road Construction, Idaho Panhandle National Forests, St. Joe Ranger District, Shoshone County, ID.

Summary: EPA expressed environmental concerns about lack of cumulative impacts analysis and adverse impacts to vegetation.

ERP No. D–BLM–K65206–NV: Rating EC2, Caliente Management Framework Plan Amendment, Implementation, Management of Desert Tortoise Habitat (Gopherus agassizii), Northeastern Mojave Recovery Unit, Lincoln County, NV.

Summary: EPA expressed environmental concerns regarding the range of alternatives selected for analysis in the DEIS, and recommended that BLM consider an alternative which would place 100% of critical habitat designated by the Fish and Wildlife Service into protected status. EPA also expressed concerns that two of the action alternatives do not appear to meet project purpose and need.

ERP No. D–COE–G11035–00: Rating LO, Programmatic—Fort Bliss Mission and Real Property Master Plan, Revised Land Use and Enhance Management of the Land, Airspace and Infrastructure, El Pasco County, TX and Dona Ana and Otero Counties, NM.

Summary: EPA had no environmental objections, and recommended selection of Alternative 3.2.

ERP No. D–NPS–K65208–CA: Rating LO, Redwood National and State Parks General Management Plan, Implementation, Humboldt and Del Norte Counties, CA.

Summary: EPA expressed a lack of objections to the project plan, but recommended that the Final EIS/EIR include specific information on the Parks' role in the total maximum daily load (TMDL) development, timber harvest plan review, and Clean Water Action Plan implementation.

ERP No. DS–BLM–J65106–CO: Rating EC2, Glenwood Springs Resource Area, Updated Information, Oil & Gas Leasing and Development, Leasing Lands in the Naval Oil Shale Reserves, Resource Management Plan Amendment, Garfield County, CO.

Summary: EPA expressed environmental concerns about adverse impact to air quality in the Flat Tops Wilderness Class 1 area. EPA recommends that a cumulative air quality impact analysis be prepared and made available to the public prior to publishing the FEIS.

ERP No. DS–BLM–J70017–MT: Rating EC2, Judith-Valley-Phillips Comprehensive Resource Management Plan, Implementation, Lewistown District, Judith Basin, Fergus, Petroleum, Phillips and Valley Counties, MT.

Summary: EPA expressed environmental concerns regarding potential adverse impact to Fisheries, Wildlife, and air and water quality, and that more data and analyses of cumulative impacts is needed.

ERP No. RD–NOA–A64058–00: Rating EC2, Calico Scallop Fishery and Sargassum Habitat Fishery, Fishery Management Plans Establishment and Implementation, South Atlantic Region.

Summary: EPA expressed environmental concerns that the Calico Scallop Fishery Management Plan contained data that was too old to fully assess impact of the fishery and collateral impacts threatened and endangered species. EPA requested that these issues be fully discussed in the next environmental document.

Final EISs

ERP No. F–BLM–L08054–AK: Northern Intertie Project, Construction of 230 kV Transmission Line from Healy to Fairbanks, AK, Application for Right-of-Way Grant, Gold Valley Electric Association, AK.

Summary: Review of the Final EIS was not deemed necessary. No formal comment letter was sent to the preparing agency.

ERP No. FS–COE–E36013–MS: Mississippi River and Tributaries Flood Control Plan, Construction of the remaining portion of the Mississippi River Mainline Levees Enlargement and Seepage Control Project, Flood Protection and Damage Reduction, Lower Mississippi River Valley, Cape Girardeau, MO to Head of Passes, LA; MO, IL, KY, TN, AR, MS and LA.

Summary: EPA continued to have environmental concerns based on the scope/duration of these projects. On-going coordination will be necessary to resolve EPA's outstanding concerns.

Dated: November 17, 1998.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 98–31094 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–5497–1]

Environmental Impact Statements; Notice of Availability

RESPONSIBLE AGENCY: Office of Federal Activities, General Information (202) 564–7167 OR (202) 564–7153.

Weekly receipt of Environmental Impact Statements Filed November 09, 1998 Through November 13, 1998 Pursuant to 40 CFR 1506.9.

EIS No. 980463, FINAL EIS, FHW, VA, Adoption—VA–168 Battlefield Boulevard South, Construction between Peaceful Road and the North Carolina State Line, Issuance of Permits, VA, Due: December 21, 1998, Contact: Edward S. Sundra (804) 281–5100.

The U.S. Department of Transportation's Federal Highway Administration has adopted the U.S. Corps of Engineers' FEIS #960421 filed on 09–06–96. FHW was not a Cooperating Agency for the above final EIS. Recirculation of the document is necessary under Section 1506.3(b) of the Council on Environmental Quality Regulations.

EIS No. 980464, DRAFT EIS, NOA, Atlantic Tunas, Swordfish and Sharks, Highly Migratory Species Fishery Management Plan, Due: January 25, 1999, Contact: Rebecca J. Lent (301) 713–2347.

EIS No. 980465, FINAL EIS, FHW, RI, Western Johnston and Cranston, Improved Highway Access to the Environmental Management District, Funding and COE Section 404 Permit, Providence County, RI, Due: December 21, 1998, Contact: Daniel J. Berman (401) 538–4541.

EIS No. 980466, FINAL EIS, AFS, AK, Crystal Creek Timber Harvest, Implementation the 1997 Tongass Land Management Plan, Stikine Area, Tongass National Forest, AK, Due: January 04, 1999, Contact: Bruce Sims (907) 772–3841.

EIS No. 980467, DRAFT EIS, FHW, MI, US 31 from I–196 in Allegan County North to I–96 in Muskegon County Improvements, NPDES Permit and COE Section 404 Permit, Allegan, Muskegon and Ottawa Counties, MI, Due: January 11, 1999, Contact: James A. Kirschensteiner, (517) 377–1880.

EIS No. 980468, DRAFT EIS, AFS, OR, Pelican Butte Ski Area Master Development Plan, Implementation, Winema National Forest, Klamath Ranger District, Klamath County, OR, Due: February 03, 1999, Contact: Don Hoffheins (541) 885–3601.

EIS No. 980469, FINAL EIS, NPS, OR, Oregon Caves National Monument, General Management Plan, Development Concept Plan, Josephine County, OR, Due: December 21, 1998, Contact: Rory D. Westberg (541) 592–2100.

EIS No. 980470, FINAL EIS, FTA, CA, Third Street Light Rail Project, Transportation Improvements, Funding, US Coast Guard Permit, and COE Section 404 Permit, San Francisco Municipal Railway, In the City and County San Francisco, CA, Due: December 21, 1998, Contact: Bob Hom (415) 744–3133.

EIS No. 980471, FINAL EIS, COE, IL, Chicagoland Underflow Plan, McCook Reservoir Construction and Operation for Temporary Retention of Floodwaters in Metropolitan Chicago, Implementation, Cook County, IL, Due: December 21, 1998, Contact: Keith Ryder (312) 353–6400.

EIS No. 980472, DRAFT EIS, FHW, NC, US 74 Shelby Bypass Transportation Improvements, Construction, Funding and COE Section 404 Permit, Cleveland County, NC, Due: January 22, 1998, Contact: Nicholas L. Graf (919) 856–4346.

Amended Notices

EIS No. 980447, FINAL EIS, CGD, CA, CA–92/San Mateo Hayward Bridge, Improvements to the East Approach and the Trestle Portion of the bridge, Coast Guard Bridge Permit and COE Section 404 Permit, Alameda and San Mateo Counties, CA, Due: December 07, 1998, Contact: Wayne Till (510) 437–3514.

Published FR–11–06–98—Correction to Title.

Dated: November 17, 1998.

William D. Dickerson,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 98–31095 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–U

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6191–7]

Investigator-Initiated Grants: Request for Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of request for applications.

SUMMARY: This document provides information on the availability of fiscal year 1999 investigator-initiated grants program announcements, in which the

areas of research interest, eligibility and submission requirements, evaluation criteria, and implementation schedules are set forth. Grants will be competitively awarded following peer review.

DATES: Receipt dates vary depending on the specific research area within the solicitation and are listed below.

FOR FURTHER INFORMATION CONTACT: U.S. Environmental Protection Agency, National Center for Environmental Research and Quality Assurance (8703R), 401 M Street SW, Washington DC 20460, telephone (800) 490–9194. The complete announcements can be accessed on the Internet from the EPA home page: http://www.epa.gov/ncerqa under ''announcements.''

SUPPLEMENTARY INFORMATION: In its Requests for Applications (RFA) the U.S. Environmental Protection Agency (EPA) invites research grant applications in the following areas of special interest to its mission: (1) Integrated Assessment of the Consequences of Climate Change, (2) Ecological Indicators, (3) Regional Scale Analysis and Assessment, (4) Urban Air Toxics, (5) Mercury: Transport and Fate through a Watershed; and (6) Decision-making and Valuation for Environmental Policy (in cooperation with the National Science Foundation). Applications must be received as follows: January 21, 1999, for topics (1) and (3); February 1, 1999, for topic (6); February 4, 1999, for topics (2) and (5); and February 18, 1999, for topic (4).

The RFAs provide relevant background information, summarize EPA's interest in the topic areas, and describe the application and review process.

Contact person for the (1) Integrated Assessment of the Consequences of Climate Change, (2) Ecological Indicators, (3) Regional Scale Analysis and Assessment, and (5) Mercury: Transport and Fate through a Watershed RFAs is Barbara Levinson (levinson.barbara@epamail.epa.gov), telephone 202–564–6911; contact person for the (4) Urban Air Toxics RFA is Deran Pashayan (pashayan.deran@epamail.epa.gov), telephone 202–564–6913; and contact persons for the (6) Decision-making and Valuation for Environmental Policy RFA is Alan Carlin (carlin.alan@epamail.epa.gov), telephone 202–260–5732, and Rachelle Hollander (rholland@nsf.gov), telephone 703–306–1743 (voice) or 703–306–0485 (FAX).

Dated: November 12, 1998.

Norine E. Noonan,

Assistant Administrator for Research and Development.

[FR Doc. 98–31072 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6191–4]

Common Sense Initiative Council (CSIC)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of Public Advisory CSI Computers and Electronics Sector, Printing Sector, Petroleum Refining Sector, and Metal Finishing Sector Subcommittee Meetings: Open Meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, Pub. L. 92-463, notice is hereby given that the Computers and Electronics Sector, the Printing Sector, Petroleum Sector and Metal Finishing Sector Subcommittees will meet on the dates and times described below. All meetings are open to the public. Seating at the meetings will be a first-come basis and limited time will be provided for public comment. For further information concerning specific meetings, please contact the individuals listed with the announcements below.

(1) Computers and Electronics Sector Subcommittee Meeting—December 2–3, 1998

Notice is hereby given that the final meeting of the Computers and Electronics Sector Subcommittee will be held in Austin, Texas, on December 2, 1998 from 8:30 a.m. to 5 p.m. CST and December 3 from 8:30 a.m. to 3 p.m. CST at the Embassy Suites Hotel-Downtown, 300 South Congress Avenue. The Subcommittee's workgroups (Reporting and Information Access; Overcoming Barriers to Pollution Prevention, Product Stewardship, and Recycling; and Alternative Strategies for Environmental Protection) will meet from approximately 9:15 a.m. until 11:45 a.m. on December 2. The full Subcommittee will convene for the remainder of the meeting. The agenda will include final reports by each of the workgroups and review of proposed recommendations to the Agency on (1) coordination of worker heath and environmental protection activities among NIOSH, EPA and OSHA, and (2) actions EPA should take to facilitate constructive engagement among stakeholders on environmental protection. The agenda will also include a discussion of the final report of the Subcommittee and a discussion of the October 15, 1998 meeting of the Common Sense Initiative Council. Opportunity for public comment on major issues will be provided at intervals throughout the meeting.

For further information concerning the meeting of the Computers and Electronics Sector Subcommittee meeting, please contact John J. Bowser, Acting DFO, U.S. EPA on (202) 260–1771, by fax on (202) 260–1096, by e-mail at bowser.john@epamail.epa.gov., or by mail at U.S. EPA (MC 7405), 401 M Street, SW, Washington, DC 20460; Mark Mahoney, U.S. EPA Region 1 on (617) 565–1155; or David Jones, U.S. EPA Region 9 on (415) 744–2266.

(2) Printing Sector Subcommittee Meeting—December 3–4, 1998

Notice is hereby given that the Environmental Protection Agency will hold an open meeting of the CSI Printing Sector Subcommittee on December 3—4, 1998. The meeting will be held on December 3 from 9 a.m. EST until 5:30 p.m. EST and on December 4 from 8:30 a.m. EST until 4 p.m. EST. The meeting will be held at the Governor's House Hotel located at 1615 Rhode Island Avenue, NW, in Washington, DC.

The purpose of the meeting will be to approve the final report on the New York City Education Project and to finalize and approve the design of the PrintSTEP project. A formal agenda will be available at the meeting.

For further information concerning meeting times and agenda of this Printing Sector Subcommittee meeting, please contact Gina Bushong, Designated Federal Officer (DFO), at EPA by telephone on (202) 564–2242 in Washington, DC, by fax on (202) 564–0009, or by E-mail at bushong.gina@epa.gov.

(3) Petroleum Refining Sector Subcommittee Meeting—December 10–11, 1998

Notice is hereby given that the Environmental Protection Agency will hold an open meeting of the Common Sense Initiative (CSI) Petroleum Refining Sector Subcommittee on December 10–11, 1998, at the Renaissance Houston Hotel, 6 Greenway Plaza East, Houston, TX 77046. The hotel telephone number is 713–629–1200. The Equipment Leaks Workgroup and Refinery Air Information Reporting System (RAIRS) Workgroup meetings will be held concurrently on Thursday, December 10 from 9 a.m. CST to 12

noon CST. After a break for lunch, the Accidental Release Information Workgroup will meet from 1:30 p.m. CST to 4:30 p.m. CST. The full Petroleum Refining Sector Subcommittee will meet from 9 a.m. CST to 4 p.m. CST on Friday, December 11, 1998.

The preliminary agenda for the Subcommittee meeting includes comments on the transition of CSI to National Advisory Council on Environmental Policy and Technology (NACEPT), and the Equipment Leaks Project Report. There will also be reports of the Accidental Release Information Project, the RAIRS Project, and the Equipment Leaks Project. A public comment period will also be provided.

For further information concerning this meeting of the Petroleum Refining Sector Subcommittee, please contact either Craig Weeks, Designated Federal Officer (DFO), at US EPA Region 6 (6EN), 1445 Ross Avenue, Dallas, TX 75202–2733, by telephone at 214–665–7505 or E-mail at weeks.craig@epamail.epa.gov or Steve Souders, Alternate DFO, at US EPA by mail (5306W), 401 M Street, SW, Washington, DC 20460, by telephone at 703–308–8431 or E-mail at souders.steve@epamail.epa.gov.

Metal Finishing Sector Subcommittee—December 15–16, 1998

Notice is hereby given that the Environmental Protection Agency will hold an open meeting of the CSI Metal Finishing Sector Subcommittee on December 15–16, 1998, at the Crowne Plaza Redondo Beach and Marina Hotel, 300 North Harbor Drive, Redondo Beach, CA 90277–2552. The telephone number to the hotel is 310–318–8888 or 1–800–368–9760. On Tuesday, December 15, 1998, the meeting will take place from 8:30 a.m. PST to 5 p.m. PST. The meeting will run from 8 a.m. to 2 p.m. on Wednesday, December 16, 1998. The Subcommittee meeting will focus on implementation of the Metal Finishing Sector's Strategic Goals Program. A formal agenda will be available at the meeting.

For further information concerning meeting times and agenda of the Metal Finishing Sector Subcommittee, please contact Bob Benson, DFO, at EPA by telephone on (202) 260–8668 in Washington, DC, by fax on (202) 260–8662, or by e-mail at benson.robert@epa.gov.

Inspection of Subcommittee Documents

Documents relating to the above topics will be publicly available at the meeting. Thereafter, these documents and the minutes of the meeting will be available for public inspection in room 3802M of EPA Headquarters, 401 M Street, SW, Washington, DC 20460, telephone number 202–260–7417. Common Sense Initiative information can be accessed electronically on our web site at http.//www.epa.gov/commonsense.

Kathleen Bailey,

Designated Federal Officer.

[FR Doc. 98–31071 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–6191–6]

Notice of Public Meeting of the National Environmental Education Advisory Council

Notice is hereby given that the National Environmental Education Advisory Council, established under section 9 of the National Environmental Education Act of 1990 (the Act), will hold a public meeting on December 10 and 11, 1998. The meeting will take place at the River Inn, 924 Twenty-Fifth Street, NW, Washington, DC from 9 a.m. to 5 p.m. on Thursday, December 10 and Friday, December 11. The purpose of this meeting is to provide the Council with an opportunity to advise EPA's Office of Communications, Education and Media Relations (OCEMR) and the Office of Environmental Education (OEE) on its implementation of the Act. Members of the public are invited to attend and to submit written comments to EPA following the meeting.

For additional information regarding the Council's upcoming meeting, please contact Ginger Keho, Office of Environmental Education (1704), Office of Communications, Education and Media Relations, U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460 or call (202) 260–4129.

Dated: November 9, 1998.

Ginger Keho,

Designated Federal Official, National Environmental Education Advisory Council.

[FR Doc. 98–31073 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30463; FRL–6043–5]

Dow AgroSciences, LLC.; Approval of Pesticide Product Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of applications to conditionally register the pesticide products Starane F Technical and Starane EC containing a new active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Hwy, Arlington, VA 22202, 703–305–6224; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the **Federal Register** Environmental Sub-Set entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

EPA received applications from Dow AgroSciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268, to conditionally register the pesticide products Starane F Technical and Starane EC (EPA File Symbols 62719–EIL and 62719–EIA), containing the active ingredient fluroxypyr 1-methylheptyl (4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyl)acetate at 98% and 26.2% respectively, an active ingredient not included in any previously registered pesticide products. However, since the notice of receipt of these applications to register the products as required by section 3(c)(4) of FIFRA, as amended did not publish in the **Federal Register**, interested parties may submit comments within 30 days from the date of publication of this notice for these products. Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. No Confidential Business Information (CBI) should be sent through e-mail.

The applications were approved on September 30, 1998, for the following products:

1. Starane F Technical for manufacturing use only (EPA Registration Number 62719–285).

2. Starane EC for postemergence control of annual and perennial broadleaf weeds and volunteer potatoes in small grains, fallow cropland, and on farm non-cropland (EPA File Registration Number 62719–286).

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain data are lacking, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects; and that use of the pesticide is in the public interest. The Agency has considered the available data on the risks associated with the proposed use of fluroxypyr 1-methylheptyl (4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyl)acetate, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health and safety determinations which show that use of fluroxypyr 1-methylheptyl (4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyl)acetate during the period of conditional registration will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is, in the public interest.

Consistent with section 3(c)(7)(C), the Agency has determined that these conditional registrations are in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

More detailed information on these conditional registrations is contained in an EPA Pesticide Fact Sheet on fluroxypyr 1-methylheptyl (4-amino-3,5-dichloro-6-fluoro-2-pyridyloxyl)acetate.

A paper copy of this fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Intregrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: November 12, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 98–31065 Filed 11–19–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30447A; FRL–6042–5]

FMC Corporation; Approval of Pesticide Product Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of applications to conditionally register the pesticide products Carfentrazone-ethyl (F8426) Technical, Aim Herbicide, and Aim 50DF containing a new active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(7)(C) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, CM #2, Environmental Protection Agency, 1921 Jefferson Davis Hwy, Arlington, VA 22202, 703–305–6224; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the **Federal Register** Environmental Sub-Set entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

EPA issued a notice, published the **Federal Register** of February 25, 1998 (63 FR 9518)(FRL–5773–6), which announced that FMC Corp., Agricultural Chemical Group, 1735 Market St., Philadelphia, PA 19103, had submitted applications to conditionally register the herbicide products Carfentrazone-ethyl (F8426) Technical, Carfentrazone-ethyl (F8426) 50DF, and Carfentrazone-ethyl (F8426) 40DF (EPA File Symbols 279–GRIR, 279–GRIE, and 279–GROU) containing the active ingredient carfentrazone-ethyl alpha,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1*H*-1,2,4-triazol-1-yl]-4-fluorobenzenepropanoate at 90%, 50%, and 40% respectively, an active ingredient not included in any previously registered pesticide products.

The applications were approved on September 30, 1998, for the products listed below:

1. Carfentrazone-ethyl (F8426) Technical for formulation use only (EPA Registration Number 279–3181).

2. Aim 50DF (formerly Carfentrazone-ethyl (F8426) 50DF) for agricultural or commercial use only to control broadleaf weeds on cereal grain groups and soybeans (EPA Registration Number 279–3182).

3. Aim 40DF (formerly Carfentrazone-ethyl (F8426) 40DF) for agricultural or commercial use only to control broadleaf weeds on cereal grain groups and soybeans (EPA Registration Number 279–3194)

A conditional registration may be granted under section 3(c)(7)(C) of FIFRA for a new active ingredient where certain data are lacking, on condition that such data are received by the end of the conditional registration period and do not meet or exceed the risk criteria set forth in 40 CFR 154.7; that use of the pesticide during the conditional registration period will not cause unreasonable adverse effects; and that use of the pesticide is in the public interest. The Agency has considered the available data on the risks associated with the proposed use of carfentrazone-ethyl, and information on social, economic, and environmental benefits to be derived from such use. Specifically, the Agency has considered the nature and its pattern of use, application methods and rates, and level and extent of potential exposure. Based

on these reviews, the Agency was able to make basic health and safety determinations which show that use of carfentrazone-ethyl during the period of conditional registration will not cause any unreasonable adverse effect on the environment, and that use of the pesticide is, in the public interest.

Consistent with section 3(c)(7)(C), the Agency has determined that these conditional registrations are in the public interest. Use of the pesticides are of significance to the user community, and appropriate labeling, use directions, and other measures have been taken to ensure that use of the pesticides will not result in unreasonable adverse effects to man and the environment.

More detailed information on these conditional registrations is contained in an EPA Pesticide Fact Sheet on carfentrazone-ethyl.

A paper copy of this fact sheet, which provides a summary description of the chemical, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Intregrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: November 9, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 98–31064 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[OPP–30454A; FRL–6041–8]

Premium Compounded LCC.; Approval of Pesticide Product Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces Agency approval of applications to register the pesticide products Migratrol R001 and Cuprous Chloride Technical, containing an active ingredient not included in any previously registered products pursuant to the provisions of section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Product Manager (PM) 22, Registration Division (7505C), Office of Pesticide Programs, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 247, Crystal Mall #2, Environmental Protection Agency, 1921 Jefferson Davis Hwy, Arlington, VA 22202, 703–305–7740; e-mail: giles-parker.cynthia@epamail.epa.gov.

SUPPLEMENTARY INFORMATION:

Electronic Availability: Electronic copies of this document and the Fact Sheet are available from the EPA home page at the **Federal Register** Environmental Sub-Set entry for this document under ''Laws and Regulations'' (http://www.epa.gov/fedrgstr/).

EPA issued a notice, published in the **Federal Register** of May 21, 1998 (63 FR 27960) (FRL–5789–1), which announced that Premium Compounded Products, LLC, Wilmington, DE 19802, had submitted applications to register the pesticide products Migratrol R001 a Manufacturing Use Product and Cuprous Chloride Technical (EPA File Symbols 71280–G and 71280–R), containing the new active ingredient cuprous chloride at 48.25% and 96.5% respectively, an active ingredient not included in any previously registered products.

The applications were approved on September 30, 1998, as Migratrol R001 and Cuprous Chloride Technical for formulating end-use plant growth regulator products only (EPA Registration Numbers 71280–3 and 71280–1), respectively.

The Agency has considered all required data on risks associated with the proposed use of cuprous chloride, and information on social, economic, and environmental benefits to be derived from use. Specifically, the Agency has considered the nature of the pesticide and its pattern of use, application methods and rates, and level and extent of potential exposure. Based on these reviews, the Agency was able to make basic health safety determinations which show that use of cuprous chloride when used in accordance with widespread and commonly recognized practice, will not generally cause unreasonable adverse effects to the environment.

More detailed information on this registration is contained in an EPA Pesticide Fact Sheet on cuprous chloride.

A paper copy of the fact sheet, which provides a summary description of the pesticides, use patterns and formulations, science findings, and the Agency's regulatory position and rationale, may be obtained from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161.

In accordance with section 3(c)(2) of FIFRA, a copy of the approved label, the list of data references, the data and other scientific information used to support registration, except for material specifically protected by section 10 of FIFRA, are available for public inspection in the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Rm. 119, CM #2, Arlington, VA 22202 (703–305–5805). Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), 401 M St., SW., Washington, DC 20460. Such requests should: (1) Identify the product name and registration number and (2) specify the data or information desired.

Authority: 7 U.S.C. 136.

List of Subjects

Environmental protection, Pesticides and pests, Product registration.

Dated: October 27, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 98–31062 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–843; FRL–6042–4]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–843, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 1132, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under **SUPPLEMENTARY INFORMATION**. No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Edward Allen	Rm. 902W16, CM #2, 703–308–8699, e-mail:allen.edward@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
Bipin Gandhi	Rm. 707A, CM #2, 703–308–8380, e-mail: gandhi.bipin@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–843] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in **ADDRESSES** at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 12, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Agrium US Inc.

PP 8F5035

EPA has received a pesticide petition (PP 8F5035) from Agrium US Inc., 4582 S. St., Suite 1400, Denver, CO 80237, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for *Pseudomonas chlororaphis Strain* 63-28 in or on the raw agricultural commodity greenhouse vegetable crops.

Pursuant to section 408(d)(2)(A)(i) of the FFDCA, as amended, Agrium US Inc. has submitted the following summary of information, data and arguments in support of their pesticide petition. This summary was prepared by Agrium US Inc. and EPA has not fully evaluated the merits of the petition. The summary may have been edited by EPA if the terminology used was unclear, the summary contained extraneuos material, or the summary was not clear that it reflected the conclusion of the petitioner and not necessarily EPA.

A. Product Name and Proposed Use Practices

Pseudomonas chloroaphis Strain 63-28 will be incorporated into the end-use product, AtEze, as an active ingredient. AtEze is proposed for use on greenhouse vegetable crops for the suppression of two important soil-borne diseases *Rhizoctonia solani* and *Pythium spp*.

The product is applied as a soil drench treatment at a dilution rate of 1:500 using potable water. In addition,

the product may also be applied with drip irrigation systems in production greenhouses.

B. Product Identity/Chemistry

Identity of the pesticide and corresponding residues. *Pseudomonas chloroaphis Strain* 63-28 is a liquid suspension containing living cells at a concentration of 109 colony forming units (cfu)/mL of fermentation product. *Pseudomonas chloroaphis Strain* 63-28 is a plant-beneficial rhizobacterium that is a non-pathogenic, non-toxic, free-living organism which is naturally occuring in soils and water worldwide.

The association of *Pseudomonas chlororaphis Strain* 63-28 with plants is adequately understood for purposes of the tolerance exemption. This rhizosphere bacterium is one of the most commonly-occurring microorganisms in soils and on roots of many plants during growing seasons. Inocula of *P. chlororaphis Strain* 63-28 applied into natural soils do not persist for a long period of time, nor do they change soil microbial processes significantly, according to published literature. Several strains of *P. chlororaphis Strain* 63-28, when introduced at a concentration of approximately 106 cfu/g of root, fall below detection levels after 8-12 weeks. There is no indication that the bacterium can be translocated in great numbers within plants. An analytical method for residues is not applicable, since the petitioner has requested an exemption from the requirement of a tolerance.

C. Toxicological Profile

Acute toxicity. AtEze, the end-use formula containing 1.15% *Pseudomonas chlororaphis Strain* 63-28, has been studied for acute toxicity. The results of these studies indicate a Toxicity Category III or IV and poses no significant human health risks. The acute oral toxicity of *Pseudomonas chlororaphis Strain* 63-28 in rats is greater than 5,000 milligrams/kilogram (mg/k)g (5.50 x 10^{10} cfu- Toxicity Category IV). Acute dermal toxicity in rabbits is greater than 2,000 mg/kg (6.82 x 10^{10} cfu-Toxicity Category III). In an eye irritation study, each rabbit received a dose of 1.06 x 10^{9} cfu viable bacteria. The highest primary irritation score observed during the study was 0.8 (out of a maximum score of 110), which was observed in a 24-hour scoring interval. No signs of ocular irritation were observed in any rabbit at the 48-hour scoring interval (Toxicity Category III). Agrium has not observed any incidents of hypersensitivity from personnel working with the product strain or the product in laboratory, fermentation facilities, greenhouses, or field studies. Their is no report in the literature to suggest that members of the species *Pseudomonas chlororaphis*, or closely related *Pseudomonads* cause any hypersensitive reaction in humans or animals.

Waivers have been requested for acute oral toxicity/pathogenicity, and acute pulmonary toxicity/pathogenicity toxicity, genotoxicity, reproductive and developmental toxicity, subchronic toxicity, chronic toxicity, and acute toxicity to nontarget species based on AtEze's ubiquity in nature, favorable toxicological profile in that *Pseudomonas chlororaphis Strain* 63-28 has never been reported as a pathogen of humans or any type of animals, other published research and toxicology studies, and inconsequential exposure resulting from label-directed uses.

D. Aggregate Exposure

1. *Dietary exposure—Food*. The estimate of aggregate exposure to *P. chlororaphis Strain* 63-28 contained in AtEze through food intake is based on potential dispersal of the bacterial to edible portions of greenhouse vegetables and on a theoretical maximum residue contribution (TMRC) to diet. The TMRC considers a maximum level of residue consumed daily if each greenhouse vegetable crop is treated with the product. According to the research data on greenhouse tomato, residual populations of the product bacterium on fruits will be less than 10 cfu /g. It is likely that residue levels on greenhouse cucumber or pepper will be similar with the same product use pattern. A very liberal estimation of daily consumption of all greenhouse vegetables is used for calculation of the TMRC. With 2 kg/day, the TMRC value would be no more than 400 cfu/kg body weight for a person weighing 50 kg. Suppose the person had the same daily intake for a life time (80 years), the accumulative amount would still be only 1.2 x 107 cfu/kg body weight, which is less than 1% of the amount used in the oral toxicity test. With the large overestimate of human dietary exposure through food, the total amount is still well below levels used, and demonstrated safe in the acute oral toxicity study. The chronic toxicity information has not been established. However, a potential residue level is so low on food crops that natural populations of the bacterium may surpass it. Therefore, a chronic toxic impact is not expected.

2. *Dietary exposure—Drinking water*. There is no maximum contaminant level established for *Pseudomonas chlororaphis Strain* 63-28 in drinking water, nor it is listed for drinking water monitoring under the Safe Drinking Water Act. The risk of contaminating well water by applied bacteria is very low because the product is used in greenhouses and the recommended amount of drench application severely limits leaching. It is expected that human exposure through drinking water is negligible. This bacterium exists in abundance in natural surface water such as ponds, lakes or streams.

3. *Non-dietary exposure*. AtEze is labeled for uses on commercial greenhouse crops only. Based on the study of persistence on several greenhouse crops, residue populations of the bacterium on the roots and in the growth medium will be negligibly low by the time of crop sales. Since the product is not found in or on fruits, and the general public has limited exposure to production greenhouses or plant growth media, the estimated non-occupational exposure to the general population is minuscule. Occupational exposure will be mitigated by the use of proper personal protective equipment and clothing.

E. Cumulative Exposure

The product strain belongs to the bacterial genus of *Pseudomonas*. Although other registered *pseudomonads* may have similar modes of action in suppressing plant diseases, there is no information available to suggest that these organisms exhibit a similar toxicity profile in the mammalian system that would be cumulative with *P. chlororaphis Strain* 63-28. Thus, consideration of a common mechanism of toxicity is not appropriate at this time. Agrium is considering only the potential risks of *P. chlororaphis* 63-28 in its aggregate exposure assessment.

F. Safety Determination

1. *U.S. population*. Based on the physical and chemical characteristics, low use rates, no evidence of any acute toxicity, lack of other toxicological concerns and a liberal estimation of exposure, Agrium believes that there is a reasonable certainty of no harm to the U.S. population in general from aggregate exposure to AtEze residue from all anticipated dietary and non-dietary exposures.

2. *Infants and children*. A developmental toxicity study was not conducted. Based on the observation that no adverse effect was found in acute toxicological studies, very low residue if any, limited exposure, and on the lack of reported concerns in the literature, Agrium believes that the product is of minimal risk.

G. Effects on the Immune and Endocrine Systems

Endocrine disruptors. Agruim has no information to suggest that *P. chlororaphis Strain* 63-28 will have an effect on the immune and endocrine systems. Furthermore, EPA is not requiring information on endocrine effects of this microbial pesticide at this time; Congress is allowing 3 years after August 3, 1996, to implement a screening program with respect to endocrine effects.

H. International Tolerances

There are no CODEX tolerances or international tolerance exemptions issued for *P. chlororaphis Strain* 63-28 at this time. (Edward Allen)

2. Rohm and Haas Company

PP 8E4952

EPA has received a pesticide petition (PP 8E4952) from Rohm and Haas Company, 100 Independence Mall West, Philadelphia, PA 19106-2399, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for Alkyl (C12-C20) Methacrylate copolymer when used in accordance with good agricultural practices as inert ingredient in pesticide formulations applied to growing crops in or on the raw agricultural commodity after harvest or to animals at parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Toxicological Profile (Low-Risk Criteria for Polymers)

In the case of certain chemical substances that are defined as ''polymers'', the Agency has established a set of criteria which identify categories of polymers that present low risk. These criteria (described in 40 CFR 723.250) identify polymers that are relatively unreactive and stable compounds compared to other chemical substances as well as polymers that typically are not readily absorbed. These properties generally limit a polymer's ability to cause adverse effects. In addition, these criteria exclude polymers about which little is known. The Agency believes that polymers meeting the criteria noted above will present minimal or no risk. Alkyl (C12-C20) Methacrylate copolymers conform to the definition of a polymer given in 40 CFR 723.250 (b) and meet the following criteria that are used to identify low risk polymers.

1. Alkyl (C12-C20) Methacrylate copolymer is not a cationic polymer, nor is it capable of becoming a cationic polymer in the natural aquatic environment.

2. Alkyl (C12-C20) Methacrylate copolymer contains as an integral part of its composition the atomic elements carbon, hydrogen, oxygen and less than 0.10% sulfur.

3. Alkyl (C12-C20) Methacrylate copolymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250 (d)(2)(iii).

4. Alkyl (C12-C20) Methacrylate copolymer is not designed, nor is it reasonably anticipated to substantially degrade, decompose or depolymerize.

5. Alkyl (C12-C20) Methacrylate copolymer is not manufactured or imported from monomers and/or other reactants that are not already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. Alkyl (C12-C20) Methacrylate copolymer is not a water absorbing polymer with a number average molecular weight greater than or equal to 10,000 daltons.

7. The minimum number-average molecular weight of Alkyl (C12-C20) Methacrylate copolymer is 50,000 daltons. Substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

8. Alkyl (C12-C20) Methacrylate copolymer has a minimum number average molecular weight of 50,000 and contains less than 2% oligomeric material below molecular weight 500 and less than 5% oligomeric material below 1,000 molecular weight.

9. Alkyl (C12-C20) Methacrylate copolymer does contain aliphatic ester groups as reactive functional groups. However, these reactive groups are not intended or reasonably anticipated to undergo further reactions under usual environmental conditions.

10. There are no evidence that Alkyl (C12-C20) Methacrylate copolymer is an endocrine disrupter, where as substances with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response.

B. Aggregate Exposure

1. *Dietary.* Alkyl (C12-C20) Methacrylate copolymer is not absorbed through the intact gastrointestinal tract and is considered incapable of eliciting a toxic response.

2. *Water.* Based upon the aqueous insolubility of Alkyl (C12-C20) Methacrylate copolymer, there is no reason to expect human exposure to residues in drinking water.

3. *Non-dietary.* Typical use of Alkyl (C12-C20) Methacrylate copolymer is in the oil industry as a wax and viscosity modifier at very low use rates. In these uses the primary exposure rate would be dermal, however, Alkyl (C12-C20) Methacrylate copolymer with a molecular weight significantly greater that 400 is not absorbed through the intact skin.

C. Cumulative Risk

There is data to support cumulative risk from Alkyl (C12-C20) Methacrylate copolymer, since polymers with molecular weights greater than 400 generally are not absorbed through the intact skin, and substances with molecular weights greater than 1,000 generally are not absorbed through the intact gastrointestinal (GI) tract. Chemicals not absorbed through the skin or GI tract generally are incapable of eliciting a toxic response. Therefore, there is no reasonable expectations of increased risk due to cumulative exposure.

D. Safety Determination

1. *U.S. population.* Alkyl (C12-C20) Methacrylate copolymer causes no safety concerns because it conforms to the definition of a low risk polymer given in 40 CFR 723.250 (b) and as such is considered incapable of eliciting a toxic response. Also, there are no additional pathways of exposure (non-occupational, drinking water, etc.) where there would be additional risk.

2. *Infants and children.* Alkyl (C12-C20) Methacrylate copolymer causes no additional concern to infants and children because it conforms to the definition of a low risk polymer given in 40 CFR 723.250 (b) and as such is considered incapable of eliciting a toxic response. Also there are no additional pathways of exposure (non-occupational, drinking water, etc.)

where infants and children would be at additional risk.

E. International Tolerances

Rohm and Haas is petitioning that Alkyl (C12-C20) Methacrylate copolymer be exempt from the requirement of a tolerance based upon the low risk polymer as per 40 CFR 723.250. Therefore, an analytical method to determine residues of Alkyl (C12-C20) Methacrylate copolymer in raw agricultural commodities has not been proposed.

We are not aware of any country requiring a tolerance for Alkyl (C12-C20) Methacrylate copolymer. Nor have there been any CODEX Maximum Residue Levels (MRL's) established for any food crops at this time. (Bipin Gandhi)

[FR Doc. 98–31068 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–846; FRL–6043–9]

BASF Corporation; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by the docket control number PF–846, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under **SUPPLEMENTARY INFORMATION.** No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Joanne I. Miller, Product Manager 23, Herbicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 237, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–6224; e-mail: miller.joanne@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–846] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–846) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 4, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

BASF Corporation

PP 6F 4604 and 4F 3041/FAP 4H5428

EPA has received pesticide petitions (PP 6F 4604 and 4F 3041/FAP 4H5428) from BASF Corporation, 26 Davis Drive, Research Triangle Park, P.O. Box 13528, NC 27709, proposing pursuant to section 408 (d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR 180.227 by establishing and revising tolerances for residues of the herbicide dicamba (3,6-dichloro-o-anisic acid) and its two metabolites; 3,6-dichloro-5-hydroxy-o-anisic acid and 3,6-dichloro-2-hydroxybenzoic acid. The tolerances requested for residues in or on the following raw agricultural commodities are described as follows:

1. Revise tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on: barley grain to 6 ppm, barley straw to 15 ppm; cottonseed to 3 ppm; wheat grain to 2 ppm, wheat straw to 30 ppm.

2. Establish new tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-o-anisic acid in or on: barley hay at 2 ppm, corn, field, forage at 3 ppm; corn, field, stover at 3 ppm, corn, pop, stover at 3 ppm;

cottonseed meal at 5 ppm; Crop Group 17 (grass forage, fodder, and hay) forage at 125 ppm and hay at 200 ppm; oats forage at 80 ppm, oats hay at 20 ppm; wheat forage at 80 ppm, wheat hay at 20 ppm.

3. Revise tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolite 3,6-dichloro-2-hydroxybenzoic acid in or on: asparagus to 4 ppm.

4. Revise tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolites; 3,6-dichloro-2-hydroxybenzoic acid and 3,6-dichloro-5-hydroxy-o-anisic acid in or on: soybean seed to 10 ppm.

5. Establish new tolerances for residues of dicamba (3,6-dichloro-o-anisic acid) and its metabolites; 3,6-dichloro-2-hydroxybenzoic acid and 3,6-dichloro-5-hydroxy-o-anisic acid in or on: aspirated grain fractions at 5,100 ppm, and soybean hulls at 13 ppm.

6. Delete the following tolerances: grasses, hay at 40 ppm; grasses, pasture at 40 ppm; and grasses, rangeland at 40 ppm as these tolerances are being replaced by Crop Group 17 in point 2.

The proposed analytical methods involve extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (gc/ecd). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. Metabolism is adequately understood on the basis of soybean, asparagus, cotton, sugarcane and published data on grass. In the majority of registered crops, the major metabolite is the 3,6 dichloro-5-hydroxy-o-anisic acid. Tolerances are expressed as the dicamba parent and/or the respective 5-hydroxy and 2-hydroxy metabolites depending on the raw agricultural commodity of concern.

2. *Analytical method*. BASF Crop, has provided suitable independently validated analytical methods for detecting and measuring levels of dicamba and its metabolites in or on food with a limit of detection that allows monitoring of food with residues at or above the levels described in these and the existing tolerances. Adequate methods are available in PAM-II for enforcement purposes. The analytical method involves extraction, partition, clean-up and detection of residues by gas chromatography/electron capture detector (gc/ecd).

3. *Magnitude of residues*—i. *Plant*. Residue trials have been conducted with dicamba on the crops for expanded use requested in the subject petitions. Multiple salts of dicamba were studied in side-by-side testing to confirm that no effect on magnitude of the residues was caused by the salt formulation type of the dicamba. The tolerances listed in the first paragraph (section 1) are based on the maximum expected residue from geographically representative field trial data.

Only newly generated data, or data not implicated in the CRAVEN Laboratories indictment are used to support the subject petitions.

ii. *Animal*. The amended uses proposed do not yield secondary residues in meat and milk above the tolerances already published under 40 CFR 180.227. Data from metabolism and feeding studies in poultry have established that the maximum expected dietary burden from crops treated with dicamba will not result in quantifiable residues above the limits of the analytical method.

B. Toxicological Profile

Data are provided that are representative of the mammalian toxicity effects of dicamba and are part of the many studies conducted to support BASF Corp. assertion of safety of dicamba to humans.

1. *Acute toxicity*—i. Oral rat LD_{50}: 1879 mg/kg (m); 1581 mg/kg (f).

ii. Acute dermal rat LD_{50}: > 2,000 kg/kg (m/f).

iii. Acute inhalation rat LC_{50}: > 9.6 mg/L (m/f).

iv. *Primary eye irritation*: Extremely irritating and corrosive to the eye.

v. *Primary dermal irritation rabbits*. Not a primary skin irritant.

vi. *Dermal sensitization guinea pigs*. Moderate potential to cause dermal sensitization.

vii. *Acute neurotoxicity*. no observed adverse effect level (NOAEL) < 300 milligrams/kilogram (mg/kg) (low dose). No neuropathological effects were found.

2. *Genotoxicty— Ames- negative*. *In vitro* chromosome aberration in Chinese Hamster Ovary: Negative; Sex-linked recessive lethal in Drosophila: Negative; Aberrations in rat bone marrow: Negative; Mitotic recombination: Negative; UDH (UDS with WI-38 human lung fibroblasts: Negative; Differential toxicity with *E. coli* polA and B. subtillus: Positive; Differential toxicity with *S. typhimurium*: Negative; UDS in human lung lymphocytes with activation: Negative; slight increase of sister chromatid exchange in human cultured lymphocytes; positive in *in vivo* unwinding of liver DNA in ip injected rats insert text.

3. *Reproductive and developmental toxicity*—Rodent Developmental Toxicity Rat: Oral doses of 0, 64, 160, or 400 mg/kg were administered daily during gestation days 6 to 19. The numbers of implantations, resorptions, and fetuses for test animals were similar to those numbers for control animals. No abnormalities were attributed to exposure to dicamba. Technical dicamba was not found to be teratogenic with the test system/study design employed. Maternal toxicity was found only at the HDT and the NOAEL was 160 mg/kg/day.

4. *Rabbit developmental toxicity*. Dicamba was administered orally (undiluted) via capsule to groups of 20 artificially inseminated New Zealand White rabbits. Dose levels of 0, 30, 150, or, 300 mg/kg were administered once daily on days 6-18 of presumed-gestation (day 0 = day of insemination). Females were sacrificed on day 29 of presumed gestation. There were no deaths attributed to treatment. At the 150 mg/kg and 300 mg/kg levels, increased numbers of does with decreased motor activity and statistically significant numbers of does with ataxia were noted. At 300 mg/kg, a significant number of does had rales and an increased number of does showed labored breathing, perinasal substance, dried feces, impaired righting reflex, and red substance in the cage pan. These clinical observations were considered to be effects of treatment. Females in the 300 mg/kg group had statistically significant body weight loss for the entire dosage period. At 150 mg/kg, females lost weight on days 7-8 of presumed gestation. Although compensatory weight gains occurred during the post-treatment period (days 19-29-of gestation), body weight gains remained statistically significantly reduced on days 6-29 of gestation in the 300 mg/kg group. No significant differences were obtained in litter averages for corpora lutea, implants, litter sizes, resorption sites, percent male fetuses, fetal body weight, percent resorbed conceptuses or number of does with any resorptions. No gross external, soft tissue or skeletal alterations in fetuses were considered to be related to treatment. The maternal NOAEL for technical dicamba to pregnant rabbits was 30 mg/kg/day. Levels of 150 and 300 mg/kg caused abortions, but were at significant maternally toxic doses. The developmental NOAEL was the highest dose tested (HDT), 300 mg/kg/day.

There were no effects on embryo-fetal viability or development at any level.

5. *2-generation reproduction rat.* Potential effects on growth and reproductive performance were assessed over 2-generations of rats maintained on diets containing Technical Dicamba at concentrations of 0 (control), 500, 1,500, or 5,000 parts per million (ppm). Exposure at 5,000 ppm was associated with a slower growth rate of F1 pups prior to weaning and resulted in lower initial body weights in those selected as parental animals. The lower body weight was associated with a decrease in both food consumption and water intake. Sexual maturation was slightly delayed among males, but was likely associated with the initial reduced growth rate. Increased liver weights were noted consistently for adults of both generations and for weanlings. There were no effects on reproductive ability from treatment at any level. The low pregnancy rate among F, females in all groups was considered to be due to increased weights of those females. The NOAEL and lowest observed adverse effect level (LOAEL) for system toxicity were 1,500 and 5,000 ppm, respectively. The NOAEL and LOAEL for reproductive toxicity were 500 (45 mg/kg/day) and 1,500 ppm, respectively.

6. *Subchronic toxicity—21 day dermal.* There were no dicamba related changes in general behavior, appearance, body weight, or in blood and urine analysis. There were no compound-related gross pathology lesions, only skin lesions. There were no significant organ weight variations observed.

7. *Thirteen-week rodent feeding-rat.* Rats were offered technical dicamba at dietary concentrations of 0, 1,000, 5,000, or 10,000 ppm. The mean body weight and food consumption values for the high dietary level animals were decreased from the control values. No adverse treatment-related findings were noted in either the blood parameters investigated or necropsy evaluation. Microscopic examinations of the liver revealed an absence or reduction of cytoplasmic vacuolation in the hepatocytes of the high dietary level animals. The NOAEL was suggested to be 5,000 ppm.

8. *Eight-week non-rodent-dog.* Technical dicamba was offered orally at dietary concentrations of 0 (Control), 100, 500, or 2,500 ppm to dogs for 1-year. Initially, a decrease in food consumption was noted mainly among males at 500 and 2,500 ppm. This was most notable in a single 2,500 ppm male resulting in almost no food consumed for the 1st 3 weeks of feeding. Following administration of the 2,500 ppm diet in a water slurry during weeks 4-6, this male was placed back on feed and food consumption stabilized. There appears to be a limit to the amount of material that can be added to the feed before dogs will not consume the diet. The 2,500 ppm level was considered close to the maximum that could be employed, as one dog failed to consume the diet when offered in the usual form. Due mainly to the aforementioned male, mean body weight of 2,500 ppm males did not increase until week 5. The overall body weight gain for the 1-year period was comparable for all groups. It was concluded that aside from the lower food consumption, the NOAEL for toxicity was 50-60 mg dicamba/kg body weight (2,500 ppm) in both males and females.

Because of the lack of toxicity shown in this study the reference dose (RfD) Peer review Committee concurred that the NOAEL was 2,500 ppm HDT and a LOAEL was not established. OPP's HED Branch is to decide if a new dog feeding study is required.

9. *Sub-chronic neurotoxicity.* NOAEL was established at 401 (M) and 472 (F) mg/kg/day. No histopathological effects on the peripheral or central nervous system were noted.

10. *Chronic toxicity—Chronic feeding/oncogenicity in rat.* Groups of 60 rats/sex were maintained on diets containing technical dicamba at concentrations of either 0, 50, 250, or 2,500 ppm. An interim sacrifice of 10/sex/level was conducted at 12 months. Initially scheduled as a 27 month study, males were sacrificed at 115-weeks and females at 118-weeks due to survival rates.

In males, no statistically significant differences in data for all tumors combined, all benign tumors combined, and all malignant tumors combined were obtained. A slight increase in malignant lymphoma was not statistically significant (pairwise comparisons) and was not considered to be toxicologically significant. A slight increase in thyroid parafollicular cell carcinoma in the high treatment group was noted but was not statistically significant in pairwise comparisons.

In females, no statistically significant differences were noted in comparisons with all tumors combined, all benign tumors combined, and all malignant tumors combined or in any individual tumor type.

In summary, no signs of toxicity related to administration of dicamba were noted. Findings among animals in the three treatment groups were considered to be comparable to findings among the control animals. Dicamba was not oncogenic for animals of the species, strain, and age under the conditions of the study. Based on the results of the study, the no effect level was considered to be 2,500 ppm.

11. *Oncogenicity in mice.* Groups of 52 male and 52 female mice were fed diets containing dicamba at oncentrations of 0, 50, 150, 1,000, or 3,000 ppm. Males were killed following 89-weeks of feeding and females were killed following 104-weeks of feeding. Reduced body weight gain (not statistically different) was noted among 3,000 ppm females. Increased mortality noted among 3,000 ppm males was considered unlikely to be related to treatment but could not be completely excluded. An increased incidence in lymphoid tumors, showing a statistical significance at 150 and 1,000 ppm, occurred in females. However, the incidence at 3,000 ppm did not statistically differ from control. Additionally, there was no significant trend with dosage and the values for treated females were within historical control data. Finally, the incidence of benign and malignant tumors in any tissue were similar for treated and control animals.

Administration of dicamba in the diet at achieved intakes ranging from 5.5 to 364 mg/kg/day produced no evidence of tumorigenic potential. Generally, no findings among mice receiving 1,000 ppm or below were considered to be of toxicological significance. The dietary level of 1,000 ppm (108 mg/kg/day in males and 121 mg/kg/day in females) was defined as the no toxic effect level.

However, the RfD committee chose to establish the NOAEL at 3,000 ppm and stated that no LOAEL had been established.

12. *Estrogenic or other ndocrine effects.* No specific tests have been conducted with dicamba to determine whether the pesticide may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effect. However, available data have not implicated dicamba in such effects.

13. *Animal metabolism.* Dicamba has been tested in rats, dogs, cattle, goats and hens. In all cases, dicamba is excreted very rapidly, mainly as unchanged dicamba and to a lesser extent as 3,6-dichloro-2-hydroxybenzoic acid with trace amounts of 3,6-dichloro-5-hydroxy-o-anisic acid. The results of these studies demonstrate that dicamba is not persistent and does not accumulate in animals.

14. *Metabolite toxicology.* Toxicity of the metabolites of dicamba to humans is concurrently evaluated during toxicity testing because both plant and animal metabolites are formed during the

course of toxicity tests. Both plant and animal major metabolites are considered not of toxicological concern.

C. Aggregate Exposure

1. *Dietary exposure*. Exposure from the use of Dicamba in the culture of wheat, barley, oats, millet, sorghum, corn, soybeans, grasses, cotton, sugarcane and asparagus crops is discussed under the below topics of food and drinking water.

2. *Food*. The subject petition amends these uses but does not add new crops. The potential dietary exposure of the population to residues of dicamba or its metabolites is calculated based on the Theoretical Maximum Residue Contribution (TMRC) for all crops with dicamba use. The TMRC is a worst case estimate of dietary exposure since it assumes that 100% of all crops for which tolerances are established are treated with dicamba, and that pesticide residues are present at the tolerance levels. The resulting dietary exposure estimate therefore overestimates exposure and is considered conservative. The number is then determined to be a percentage of the EPA decided RfD. Dietary exposure may occur from crop commodities and meat and milk. Based on the EPA DRES model BASF Corp. has estimated that the average U.S. population dietary exposure to dicamba to be only 1.87% of the RfD. This number is very low and considered very safe as an active ingredient is allowed up to 100% before less conservative risk assessment measures are initiated.

Acute dietary analysis compared the daily dietary exposure to the lowest NOAEL for acute and subchronic studies. EPA's current policy for Tier I analysis uses the conservative assumption that all residues are at a high end estimate or maximum, typically taken as the tolerance value. Acute dietary assessment for dicamba is made by comparing the ratio of exposure and the NOAEL from acute neurotoxicity of 300 mg/kg/day to achieve a Margin of Exposure (MOE). A MOE of 300 is required because a NOAEL was not reached in the acute neurotoxicity test. The following MOE values are obtained for key population subgroups.

Population Subgroup	Margin of Exposure
US Population	16000
Infants <1 year	13000
Children 1 to 6	13000
Females 13+ years	117000
Males 13+ years	110000

3. *Drinking water*. Dicamba has been used commercially for in excess of 30 years. From available public data, detections in ground water from commercial uses have been very low and infrequent. The typical level found in ground water is less than 5 ppb. This should be compared to the current Health Advisory Level (HAL) of 200 ppb and the anticipated HAL of 3,000 ppb under the newly revised RfD of 0.45 mg/kg/day.

These infrequent and low levels of detection in groundwater demonstrate that significant movement of dicamba is not likely and is not a considerable factor in assessing human health risk.

4. *Non-dietary exposure*. Non-dietary exposure would mainly occur from the use of dicamba for broadleaf weed control on residential or recreational turf. BASF is currently collecting data on the potential exposure from non-dietary sources such as residential turf use. However, no reliable information are currently available for risk assessment at this time. This petition is only related to already approved crop uses and therefore non-dietary route of exposure is not considered to be a factor in assessing additional human risk.

D. Cumulative Effects

Dicamba belongs to the benzoic acid class of compounds. There are no other compounds of this class in significant use and none in food use. Therefore, cumulative effects from dietary or non-occupational exposure from pesticides of similar chemistry are considered unlikely. BASF Corp. does not have reliable data to indicate a common mechanism of toxicity to other compounds. Therefore cumulative effects from common mechanisms of action are also unlikely.

E. Safety Determination

The RfD for dicamba is 0.45 mg/kg/day. The RfD is a level at or below which daily aggregate exposure over a lifetime will not cause appreciable human health risk. The estimates of exposure are based on conservative assumptions that all crops with a tolerance for dicamba are treated and that all residues found are at the maximum or tolerance level.

1. *U.S. population*. Using the conservative assumptions described above, BASF Corp. has estimated that the U.S. population dietary exposure to dicamba is 1.87% of the RfD.

2. *Infants and children*. Dicamba is not a reproductive or developmental toxicant. Therefore no specific effects on infants and children are expected. Based on the weight of evidence of the toxicity studies an additional safety factor is not warranted.

Using the conservative assumptions described above, BASF Corp. has estimated the dietary exposure to infants and children as percent of the RfD. From the current and new proposed use of dicamba dietary exposure for the most sensitive subgroups are 6.65% for non-nursing infants (<1-year old) and 4.6% for children 1-6 years old.

Aggregate exposure due to the combined residues in food, drinking water and non-dietary exposure through direct contact with residues in a residential setting (lawn) should be pursued through the use of a reserve risk approach. The elements for consideration are therefore estimated as follows:

- Food: Total Population 1.87%
  Non-nursing Infants <6yrs. 6.7%
- Water/Lawn: Low human risk.....expected to be inconsequential

BASF Corp. believes that the water and non-dietary exposure risk for the most sensitive subgroup is inconsequential due to demonstrated low findings in water relative to the HAL and low toxicity to humans with respect to oral, dermal and inhalation exposure.

Aggregate exposure is therefore estimated to be less than 10% of the RfD for the most sensitive population subgroup. Therefore, BASF Corp. concludes that there is reasonable certainty that no harm will result from aggregate exposure of residues of dicamba or its metabolites including all dietary and other non-occupational exposures.

F. International Tolerances

No international tolerances have been established under CODEX. Therefore there is no need to ensure consistency.

[FR Doc. 98–31070 Filed 11–19–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–836; FRL–6030–9]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–836, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 1132 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: The product manager listed in the table below:

Product Manager	Office location/telephone number	Address
Mark Dow PM-03	Rm. 214, CM #2, 703–305–5533, e-mail:dow.mark@epamail.epa.gov.	1921 Jefferson Davis Hwy, Arlington, VA
James Tompkins PM-25	Rm. 239, CM #2, 703–305–5697, e-mail:tompkins.james@epamail.epa.gov.	Do.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–836] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comments and data will also be accepted on disks in Wordperfect 5.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket number (insert docket number) and appropriate petition number. Electronic comments on notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 27, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Bayer Corporation

PP 8F5023

EPA has received a pesticide petition (PP 8F5023) from Bayer Corporation, 8400 Hawthorn Road, Kansas City, MO 64120, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of cyfluthrin: [cyano[4-fluoro-3-phenoxyphenyl]-methyl-3-[2,2-dichloroethenyl]-2,2-dimethyl-cyclopropanecarboxylate] in or on the raw agricultural commodity soybean, bean at 0.03 parts per million (ppm); soybean, forage at 8.0 ppm; soybean, hay at 4.0 ppm; field corn, forage at 3.0 ppm; and field corn, fodder at 6.0 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism of cyfluthrin in plants is adequately understood. Studies have been conducted to delineate the metabolism of radiolabeled cyfluthrin in various crops all showing similar results. The residue of concern is cyfluthrin.

2. *Analytical method*. Adequate analytical methodology (gas/liquid chromatography with an electron capture detector) is available for enforcement purposes.

3. *Magnitude of residues*. Cyfluthrin is the active ingredient in the registered end-use product Baythroid 2 Emulsifiable Pyrethroid Insecticide, EPA Reg. No. 3125-351. Data to support the proposed tolerances have been submitted to the Agency.

B. Toxicological Profile

1. *Acute toxicity*. There is a battery of acute toxicity studies for cyfluthrin supporting an overall toxicity Category II for the active ingredient.

2. *Genotoxicty*. Mutagenicity tests were conducted, including several gene mutation assays (reverse mutation and recombination assays in bacteria and a Chinese hamster ovary (CHO)/HGPRT assay); a structural chromosome aberration assay (CHO/sister chromatid exchange assay); and an unscheduled DNA synthesis assay in rat hepatocytes. All tests were negative for genotoxicity.

3. *Reproductive and developmental toxicity*. An oral developmental toxicity study in rats with a maternal and fetal no observed adverse effect level (NOAEL) of 10 milligram/kilogram body weight/day (mg/kg/bwt/day) highest dose tested (HDT).

An oral developmental toxicity study in rabbits with a maternal NOAEL of 20 mg/kg/bwt/day and a maternal lowest effect level (LEL) of 60 mg/kg/bwt/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg/bwt/day and a fetal LEL of 60 mg/kg/ bwt/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

A 3-generation reproduction study in rats with systemic toxicity NOAELs of 7.5 and 2.5 mg/kg/bwt/day for parental animals and their offspring, respectively. At higher dose levels (HDLs), the body weights of parental animals and their offspring were reduced.

4. *Subchronic toxicity*. A subchronic toxicity feeding study using rats demonstrated a NOAEL of 22.5 mg/kg/ bwt/day, the HDT.

A 6 month toxicity feeding study in dogs established a NOAEL of 5 mg/kg/ bwt/day. The LEL was 15 mg/kg/bwt/ day based on clinical signs and reduced thymus weights.

5. *Chronic toxicity*. A 12 month chronic feeding study in dogs established a NOAEL of 4 mg/kg/bwt/ day. The LEL for this study is established at 16 mg/kg/bwt/day, based on slight ataxia, increased vomiting, diarrhea and decreased body weight.

A 24 month chronic feeding/ carcinogenicity study in rats demonstrated a NOAEL of 2.5 mg/kg/ bwt/day and LEL of 6.2 mg/kg/bwt/day, based on decreased body weights in males, decreased food consumption in males, and inflammatory foci in the kidneys in females.

A 24 month carcinogenicity study in mice was conducted. Under the conditions of the study there were no carcinogenic effects observed. A 24 month chronic feeding/carcinogenicity study in rats was conducted. There were no carcinogenic effects observed under the conditions of the study.

6. *Animal metabolism*. A metabolism study in rats showed that cyfluthrin is rapidly absorbed and excreted, mostly as conjugated metabolites in the urine, within 48 hours. An enterohepatic circulation was observed.

7. *Metabolite toxicology*. No toxicology data have been required for cyfluthrin metabolites. The residue of concern is cyfluthrin.

8. *Endocrine disruption*. There is no evidence of endocrine effects in any of the studies conducted with cyfluthrin, thus, there is no indication at this time that cyfluthrin causes endocrine effects.

C. Aggregate Exposure

1. *Dietary exposure— Food*. Dietary exposure was estimated using Novigen's Dietary Exposure Evaluation Model (DEEM) software; results from field trial and processing studies; consumption data from the USDA Continuing Surveys of Food Intake by Individuals (CSFIIs), conducted from 1989 through 1992; and information on the percentages of crops treated with cyfluthrin.

Cyfluthrin is currently registered for use in alfalfa, carrots, citrus, cotton, peppers, radishes, sorghum, sunflower, sugarcane, sweet corn, and tomatoes. In addition, it has an import tolerance for hops. Various formulations are registered for use in food handling establishments and in combination with another active ingredient, for use in field corn, pop corn and sweet corn. For potential cyfluthrin use on soybeans and field corn the impact on the exposure assessment was examined.

Chronic dietary exposure estimates with the current label uses for the overall U.S. population were 0.9% of the reference dose (RfD) (0.008 mg/kg/ bwt/day). When soybeans, field corn and potatoes were included the chronic dietary exposure estimates for the overall U.S. population were 0.8% of the RfD. For the most highly exposed population subgroups, non-nursing infants (<1 year) and children 1 to 6 years of age, the exposure was estimated to be 1.9% of the RfD and 1.8% of the RfD respectively for current label uses and 1.7% of the RfD and 1.7% of the RfD respectively for label uses plus potatoes, soybeans, field corn. The apparent drop in the percentage of the RfD when these uses are added may be explained by the lower limit of detection of the field trial data for these crops as opposed to the food handling data.

Acute dietary exposures were estimated for the overall U.S. population, females 13 years and older, children, ages 1-6, and 7-12 years, infants, non-nursing and nursing. The exposure was compared to the NOAEL of 20 mg/kg/ bwt/day to estimate the margin of exposures (MOEs).

For the all the population subgroups studies the 95th and 99.9th percentile of exposure the MOEs were calculated to be over 18,000 and 5,000 respectively for all current label uses and 9,900 and 3,800 respectively for all label uses plus potatoes, field corn and soybeans.

For women aged 13 years and older the 95th, and 99.9th percentile of acute exposure the MOEs were calculated as 66,746 and 18,390 respectively for all current label uses and 33,704 and 11,516 respectively for label uses plus potatoes, field corn, and soybeans.

Lastly, for the potentially highest exposed population subgroups, non-nursing infants (<1 year) and children ages 1-6 years, the 95th, and 99.9th percentile of acute exposure to the MOEs were calculated at 53,356; 18,346 and 5,179; 6,319 respectively for all current label uses and 19,624; 9,964 and 3802; 3943 respectively for label uses plus potatoes, field corn, and soybeans.

2. *Drinking water*. Cyfluthrin is immobile in soil, therefore, will not leach into groundwater. Additionally, due the insolubility and lipophilic nature of cyfluthrin, any residues in surface water will rapidly and tightly bind to soil particles and remain with sediment, therefore not contributing to potential dietary exposure from drinking water.

A screening evaluation of leaching potential of a typical pyrethroid was conducted using EPA's Pesticide Root Zone Model (PRZM3). Based on this screening assessment, the potential concentrations of a pyrethroid in ground water at 2 meters are essentially zero <0.001 parts per billion (ppb). Surface water concentrations for pyrethroids were estimated using PRZM3 and Exposure Analysis Modeling System (EXAMS) using standard EPA cotton runoff and Mississippi pond scenarios. The maximum concentration predicted in the simulated pond was 52 parts per trillion (ppt). Concentration in actual drinking water would be much lower. Based on these analyses, the contribution of water to the dietary risk estimate is negligible.

3. *Non-dietary exposure*. Non-occupational exposure to cyfluthrin may occur as a result of inhalation or contact from indoor residential, indoor commercial, and outdoor residential uses. Pursuant to the requirements of Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA) as amended by the Food Quality Protection Act (FQPA) of 1996 non-dietary and aggregate risk analyses for cyfluthrin were conducted. The analyses include evaluation of potential non-dietary acute application and post-application exposures. Non-occupational, non-dietary exposure was assessed based on the assumption that a flea infestation control scenario represents a ''worst case'' scenario. For the flea control infestation scenario indoor fogger, and professional residential turf same day treatments were included for cyfluthrin. Deterministic (point values) were used to present a worse case upper-bound estimate of non-dietary exposure. The non-dietary exposure estimates were expressed as systemic absorbed doses for a summation of inhalation, dermal, and incidental ingestion exposures. These worst-case non-dietary exposures were aggregated with chronic dietary exposures to evaluate potential health risks that might be associated with cyfluthrin products. The chronic dietary exposures were expressed as an oral absorbed dose to combine with the non-dietary systemic absorbed doses for comparison to a systemic absorbed dose NOAEL. Results for each potential exposed subpopulation (of adults, children 1-6 years, and infants <1 year) were compared to the systemic absorbed dose NOAEL for cyfluthrin to provide estimates of MOE.

The large MOEs for cyfluthrin clearly demonstrate a substantial degree of safety. The total non-dietary MOEs are 3,800, 2,700, and 2,500 for adults, children (1-6 years), and infants (<1 year), respectively. The aggregate MOE for adults is approximately 3,700 and the MOEs for infants and children exceed 2,400.

The non-dietary methods used in the analyses can be characterized as highly conservative. This is due to the conservatism inherent in the calculation procedures and input assumptions. An example of this is the conservatism inherent in the jassercise methodology's over-representation of residential post-application exposures. It is important to acknowledge that these MOEs are likely to significantly underestimate actual MOEs due to a variety of conservative assumptions and biases inherent in the derivatization of exposure by this method. Therefore, it can be concluded that large MOEs associated with potential non-dietary and aggregate exposures to cyfluthrin will result in little or no health risks to exposed persons. The aggregate risk analysis demonstrates compliance with the health-based requirements of the FQPA of 1996 for the current label uses. The additional use of cyfluthrin on field corn and soybean crops will have no impact on the analysis for non-dietary exposure.

D. Cumulative Effects

Bayer will submit information for EPA to consider concerning potential cumulative effects of cyfluthrin consistent with the schedule established by EPA at 62 FR 42020 (August 4, 1997) and other EPA publications pursuant to the FQPA.

E. Safety Determination

1. *U.S. population*. Based on the exposure assessments described above and on the completeness and reliability of the toxicity data, it can be concluded that total aggregate exposure to cyfluthrin from all label uses plus soybeans and field corn will utilize less than 2% of the RfD for chronic dietary exposures and that MOE in excess of 1,000 exist for aggregate exposure to cyfluthrin for non-occupational exposure. EPA generally has no concerns for exposures below 100% of the RfD, because the RfD represents the level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. MOE of 100 or more (300 for infants and children) also indicate an adequate degree of safety. Thus, it can be concluded that there is a reasonable certainty that no harm will result from aggregate exposure to cyfluthrin residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of cyfluthrin, the data from developmental studies in both rat and rabbit and a 2-generation reproduction study in the rat can be considered. The developmental toxicity studies evaluate any potential adverse effects on the developing animal resulting from pesticide exposure of the mother during prenatal development. The reproduction study evaluates any effects from exposure to the pesticide on the reproductive capability of mating animals through 2-generations, as well as any observed systemic toxicity. The toxicology data which support these uses of cyfluthrin include:

i. A rat oral developmental toxicity study in which maternal and fetal NOAELs of 10 mg/kg/bwt/day HDT were observed.

ii. An oral developmental toxicity study in which rabbits had a maternal NOAEL of 20 mg/kg/bwt/day and a maternal LEL of 60 mg/kg/bwt/day, based on decreased body weight gain and decreased food consumption during the dosing period. A fetal NOAEL of 20 mg/kg/bwt/day and a fetal LEL of 60 mg/kg/bwt/day were also observed in this study. The LEL was based on increased resorptions and increased postimplantation loss.

iii. An oral developmental toxicity study performed with beta-cyfluthrin, the resolved isomer mixture of cyfluthrin, has been submitted to the Agency and is currently under review.

iv. A developmental toxicity study in rats exposed via inhalation to liquid aerosols of cyfluthrin revealed developmental toxicity, but only in the presence of maternal toxicity. The developmental NOAEL was 0.46 mg/m3 on the basis of reduced placental and fetal weights, and delayed ossification. The NOAEL for overt maternal toxicity was <0.46 mg/m3, the lowest dose tested (LDT).

In a rat 3-generation reproduction study, systemic toxicity NOAELs of 7.5 and 2.5 mg/kg/bwt/day for parental animals and their offspring, respectively, were observed. At higher dose levels, the body weights of parental animals and their offspring were reduced. Another multiple-generation reproduction study in rats has been submitted to the Agency and is currently under review.

To assess acute dietary exposure and determine a MOE for the overall U.S. population and certain subgroups, the Agency has used the rabbit developmental toxicity study which had a maternal NOAEL of 20 mg/kg/bwt/day. Because the toxicological endpoint is one of developmental toxicity, the population group of concern for this analysis was women aged 13 and above. This subgroup most closely approximates women of child-bearing age. The MOE is calculated as the ratio of the NOAEL to the exposure. The Agency calculated the MOE to be over 600. Generally, MOE's greater than 100 for data derived from animal studies are regarded as showing no appreciable risk.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children. The additional safety factor may be used when pre- and post-natal threshold effects were observed in studies or to account for incompleteness of the toxicity database.

The results of the 3-generation study in rats provided evidence suggesting that, with respect to effects of cyfluthrin on body weight, pups were more sensitive than adult rats. Thus, the Agency determined that an additional 3-fold uncertainty factor (UF) should be used in risk assessments to ensure adequate protection of infants and children.

Generally, the EPA considers MOE of at least 100 to indicate an adequate degree of safety. With an additional 3x UF, this would be 300 for infants and children. Using the exposure assessments described above and based on the described toxicity data aggregate exposure to infants and children indicate a margin of exposure in excess of 3,800. Thus, it can be concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to cyfluthrin residues.

F. Conclusions

The available data indicate that there is reasonable certainty of no harm from the aggregate exposure from all currently registered uses of cyfluthrin plus potatoes, field corn and soybeans.

G. International Tolerances

There are no Codex maximum residue levels (MRLs) currently established for residues of cyfluthrin on soybean commodities. There is a Codex MRLs for maize of 0.05 ppm.

2. Dow AgroSciences

PP 6F4784, PP 7F4856

EPA has received pesticide petitions (PP 6F4784 and PP 7F4856) from Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268-1054, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide diclosulam (N-(2,6-dichlorophenyl)-5-ethoxy-7-fluoro[1,2,4]triazolo[1,5-c]pyrimidine-2-sulfonamide) in or on the raw agricultural commodities soybean and peanut at 0.02 parts per million (ppm). EPA has determined that the petitions contain data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petitions.

A. Residue Chemistry

1. *Plant metabolism*. Nature of residue studies demonstrated that residues of diclosulam would not be expected to accumulate to significant levels in soybeans or peanuts grown on soil treated with diclosulam, and that it was appropriate to base the magnitude of total terminal residues and proposed tolerances only on residues of the parent compound, diclosulam.

2. *Analytical method*. Analytical method is available for the determination of diclosulam in soybeans and peanuts at a limit of quantitation (LOQ) of 0.01 ppm that is suitable for the enforcement of the proposed tolerance of 0.02 ppm.

3. *Magnitude of residues*. No detectable residues of diclosulam are expected to result from soil applications to fields intended for soybeans or peanuts under the proposed maximum label conditions. On the basis of the limit of detection (LOD) of 0.003 ppm for diclosulam in the analytical method, a tolerance of 0.02 ppm is proposed for soybeans and peanuts. Soybeans and peanuts treated with 3 times the maximum label rates also resulted in no detectable residues of diclosulam in the soybean and peanuts or processed meal and oils. Thus, no tolerances are being proposed for diclosulam in any processed products.

B. Toxicological Profile

1. *Acute toxicity—Diclosulam acute toxicity is low*. The acute oral LD_{50} in the rat is >5,000 milligrams/kilogram (mg/kg) in both males and females and the acute dermal LD_{50} in the rabbit is >2,000 mg/kg. The inhalation LC_{50} in the rat is >5.04 mg/l of air. Diclosulam produced no indications of dermal irritation in rabbits or sensitization in the guinea pig, and only very slight transient eye irritation in the rabbit following acute exposure. End use formulations of diclosulam have similar low acute toxicity profiles.

2. *Genotoxicty*. In a battery of short-term *in vitro* genotoxicity tests (Ames, CHO/HGPRT, chromosomal aberration) and an *in vivo* cytogenetic assay, diclosulam was negative.

3. *Reproductive and developmental toxicity*. Diclosulam exhibited no effects on reproduction or fetal development. No effects on reproduction or fetal development in a multigeneration reproduction study in rats and no effects on reproductive performance or neonatal survival were seen at the highest dose tested (HDT) (limit test at 1,000 milligrams/kilogram/day (mg/kg/day). In a developmental toxicity study in rabbits, the maternal no observed adverse effect level (NOAEL) was 65 mg/kg/day and the developmental NOAEL was at least 650 mg/kg/day.

4. *Subchronic toxicity*. Thirteen-week dietary toxicity studies in rats, mice and dogs were conducted. The primary target organs identified in these studies were the kidneys (rat), and the liver (rat, mouse and dog). In the rat 13-week study the NOAELs were 50 mg/kg/day in the male and 100 mg/kg/day in the female, based on liver histopathologic evaluation in males and decreased body weights in females. In the mouse, the NOAEL was 100 mg/kg/day based upon hepatocellular hypertrophy. An NOAEL of 5 mg/kg/day was established in the dog based upon centrilobular hepatocellular hypertrophy at 25 mg/kg/day. In a 21-day repeated dermal application study in rabbits, diclosulam when given at a dose of 1,000 mg/kg/day produced no signs of dermal irritation or systemic toxicity.

5. *Chronic toxicity*. In a 2-year combined chronic toxicity/oncogenicity study in the rat, the NOAEL for chronic toxicity was 5 mg/kg/day based upon kidney effects characterized as slight, subtle alteration in kidney tubular morphology, mostly within the corticomedullary junction which likely represented more a physiologic adaptation than a pathological change indicative of a toxic injury. There was no evidence of an oncogenic response. In a 2-year dietary feeding study in B6C3F1 mice conducted at 50, 100, 250 and 500 mg/kg/day, 50 mg/kg/day was considered the NOAEL in males and the NOAEL in females based upon histologic changes in the kidney. The lesion noted in male mice was a reduced vacuolation of the kidney tubular epithelium at all dose levels. Decreased absolute and relative kidney weights were seen at 100 mg/kg/day and above. In female mice, focal dilation with hyperplasia of the lining epithelium of the renal cortical tubules was seen at 100 mg/kg/day and above. There was no evidence of an oncogenic response. In a 1-year chronic toxicity study in dogs, the NOAEL was considered 25 mg/kg/day, the HDT. Measurable toxicity was anticipated based on the results of the 13-week study in dogs; however, the only treatment related effects were slight elevations in serum alkaline phosphatase and creatinine levels at 25 mg/kg/day, which were considered within the normal limits of variability in dogs.

6. *Animal metabolism*. Metabolism studies conducted on diclosulam indicated over 80% of a single or repeated dose of 5 mg/kg was absorbed, while at 500 mg/kg/day, there was incomplete absorption of diclosulam, with only 15-20% of the dose absorbed. Urinary elimination was rapid with half-lives of approximately 7-12 hours. Sex dependent differences in disposition of the 5 mg/kg dose were traced to more efficient elimination of unchanged diclosulam in the female versus male kidney but are of no known toxicologic significance. Due to its rapid elimination, diclosulam has little potential to accumulate upon repeated administration.

7. *Metabolite toxicology*. The residue of concern for tolerance setting purposes is the parent material (diclosulam). Thus, there is no need to address metabolite toxicity.

C. Aggregate Exposure

1. *Dietary exposure—Food*. For Purposes of assessing the potential dietary exposure from use of diclosulam on soybeans and peanuts, a conservative estimate of aggregate exposure is determined by Theoretical Maximum Residue Contribution (TMRC) assuming that 100% of the soybeans and peanuts have a residue of diclosulam at the proposed tolerance level of 0.02 ppm. This results in an extremely conservative estimate of exposure for diclosulam, because no residues are expected in these commodities at the proposed maximum label rate. The potential dietary exposure is obtained by multiplying the tolerance residue level on soybeans and peanuts (0.02 ppm) by the consumption data which estimates the amount of soybean and peanut products consumed by various population subgroups. The maximum potential average daily dose (ADD) of diclosulam values determined for various populations are clearly significant overestimates compared with actual exposure. When ADDs are compared to the Reference Dose (RfD), which uses the lowest NOAEL of 5 mg/kg/day from the 2-year rat chronic toxicity study and an uncertainty factor of 100, the ADD for all U.S. consumers including the highest exposed group, non-nursing infants under 1-year old, would theoretically be exposed to about 0.1% of the RfD.

2. *Drinking water*. Another potential source of dietary exposure are residues in drinking water. Based upon the available field dissipation and field run off studies conducted with diclosulam there is little potential for exposure to diclosulam in drinking water to cause any human health concern.

D. Cumulative Effects

There is no reliable information to indicate that diclosulam has a common mechanism of toxicity with any other chemical compound or that potential toxic effects of diclosulam would be cumulative with those of any other pesticide chemical. Thus Dow AgroSciences believes it is appropriate to consider only the potential risks of diclosulam in its exposure assessment.

E. Safety Determination

1. *U.S. population*. Using the conservative exposure assumptions described above, and based on the completeness and reliability of the toxicity data, Dow AgroSciences has concluded that aggregate exposure to diclosulam potentially can utilize about 0.1% of the RfD for non-nursing infants under 1-year old, theoretically the most exposed population. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Therefore, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result from aggregate exposure to diclosulam residues in on soybeans and peanuts and its processed products.

The complete toxicology profile for diclosulam shows no evidence of physiological effects characteristic of the disruption of the hormone estrogen. Based upon this observation, diclosulam does not meet the criteria for an estrogenic compound.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of diclosulam, data from developmental toxicity studies in rats and rabbits and a multigeneration reproduction study in the rat are considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability and potential systemic toxicity of mating animals and on various parameters associated with the well-being of offspring.

FFDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the data base. Based on the current toxicological data requirements, the data base for diclosulam relative to pre- and post-natal effects for children is complete. Further, for diclosulam, the NOAEL in the chronic feeding study which was used to calculate the RfD (5 mg/kg/day) is already lower than the NOAELs from the developmental studies in rats and rabbits by a factor of more than 200-fold.

Concerning the reproduction study in rats, there were no effects on reproduction or fetal development, even at a dose over 100 times the NOAEL used to establish the RfD. Therefore, Dow AgroSciences concludes that an additional uncertainty factor is not needed and that the RfD at 0.05 mg/kg/day is appropriate for assessing risk to infants and children.

Using the conservative exposure assumptions previously described, the percent RfD utilized by the aggregate (diet, and drinking water) exposure to residues of diclosulam on soybeans and peanuts is 0.000051 mg/kg/day for non-nursing infants under 1-year old, theoretically the most exposed population subgroup. Thus, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, Dow AgroSciences concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to diclosulam on soybeans and peanuts.

F. International Tolerances

There are no Codex maximum residue levels established for residues of diclosulam on soybeans, peanuts or any other food or feed crop.

[FR Doc. 98–31066 Filed 11–19–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–840; FRL–6039–6]

Dow AgroSciences LLC; Pesticide Tolerance Petition Filing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by the docket control number PF–840, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted

through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: James A. Tompkins, Herbicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 305–5697; e-mail: tompkins.jim@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–840] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–840) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 22, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the views of the petitioner. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Dow AgroSciences LLC

PP 4F4412

On May 13, 1997 (62 FR 26305) EPA published a notice that EPA had received pesticide petition (PP 4F4412) from Dow AgroSciences, 9330 Zionsville Road, Indianapolis, IN 46268-1054, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for inadvertent residues of the herbicide picloram in or on the raw agricultural commodity grain sorghum grain, forage, and stover at 0.3, 0.2, and 0.5 parts per milliom (ppm), respectively. No comments were received to the initial notice of filing. This notice announces that the petition was amended by also proposing to establish a tolerance for residues of the herbicide picloram in or on the raw agricultural commodity aspirated grain fractions at 4 ppm. The analytical method is Method A and III listed in the Pesticide Analytical Manual (PAM), Vol. II. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residue in plants is understood based on a wheat metabolism study. The residue of concern in wheat forage, straw and grain is conjugated picloram, which is hydrolyzable by acid, base and B-glucosidase. The minor metabolites that were identified in grain and straw were 4-amino-6-hydroxy-3,5-dichloropicolinic acid and 4-amino-2,3,5-trichloropyridine.

2. *Analytical method*. The analytical portions of the magnitude of residue studies were performed at Dow AgroSciences in Midland, MI. The analytical method utilized for the determination of picloram residue levels in the submitted studies was ACR 73.3.S2. There is a practical analytical method for detecting and measuring levels of picloram in or on food with a limit of quantitation that allows monitoring of food with residues at or above the levels set in these tolerances. EPA has provided information on this method to FDA. The method is available to anyone who is interested in pesticide residue enforcement.

3. *Magnitude of residues*.

SUMMARY OF RESIDUES OF PICLORAM (PPM) FOUND IN GRAIN SORGHUM

Matrix	Range
Grain	ND[a]-0.23
Forage	ND-0.17
Fodder	ND-0.44

[a]ND = less than one-half of the validated lower limit of quantitation of 0.05 μg/g in grain and 0.1 μg/g in forage and fodder.

B. Toxicological Profile

1. *Acute toxicity*. Studies for acute toxicity indicate that picloram is classified as category III for acute oral toxicity, category III for acute dermal toxicity, category I/II (depending on whether acid or salts) for acute inhalation toxicity, category IV for skin irritation potential, and category III for eye irritation potential. The potassium salt is classified as a skin sensitizer. In addition, picloram has a low vapor pressure.

Picloram potassium salt has low acute toxicity. The rat oral LD_{50} is 3,536 milligrams/kilogram (mg/kg) or greater for males and females. The rabbit dermal LD_{50} is >2,000 mg/kg and the rat inhalation LC_{50} is >1.63 mg/L air (the highest attainable concentration).

Picloram potassium salt is a positive skin sensitizer in guinea pigs but is not a dermal irritant. Technical picloram potassium salt is a moderate ocular irritant but ocular exposure to the technical material would not normally be expected to occur to infants or children or the general public. End use formulations of picloram have similar low acute toxicity profiles plus low ocular toxicity as well. Therefore based on the available acute toxicity data, picloram does not pose any acute dietary risks.

2. *Genotoxicty*. Picloram acid was evaluated in the Ames test using *Salmonella typhimurium*. Doses ranged up to 5,000 µg/plate, with and without metabolic activation. The test substance did not produce a mutagenic response either in the presence or absence of activation.

Picloram acid was evaluated for gene mutation in mammalian cells (HGPRT/CHO). As evaluated up to toxic levels (1,750 µg/ml without metabolic activation; 4,500 µg/ml with metabolic activation), the compound was found to be negative for inducing forward mutation in Chinese hamster ovary (CHO) cells.

Picloram acid was evaluated for cytogenetic effects on bone marrow cells of rats via intra gastric administration at dosage levels of 0 (vehicle), 20, 200 or 2,000 mg/kg. The test material did not produce cytogenetic effects in the study.

Picloram acid was evaluated for genotoxic potential as administered to primary rat hepatocyte cultures at concentrations of 0 (vehicle), 10, 33.3, 100, 333.3 or 1,000 µg/ml. The test material was negative for unscheduled DNA synthesis (UDS, a measure of DNA damage/repair) treated up to cytotoxic levels of (1,000 µg/ml).

3. *Reproductive and developmental toxicity*. The HED reference dose (RfD) Peer Review Committee concluded that there was no evidence, based on the available data, that picloram and its salts were associated with significant reproductive or developmental toxicity under the testing conditions.

In the following developmental toxicity studies, the dose levels that appear in parenthesis are picloram acid equivalents where the conversion factor employed was 0.86 as applied to doses of potassium salt.

Picloram potassium salt was administered to New Zealand rabbits by oral gavage at dosage levels of 0, 40, 200 and 400 mg/kg/day (picloram acid equivalents) during days 6 to 18 of gestation. The maternal no observed adverse effect level (NOAEL) is 40 (34) mg/kg/day, where the lowest observed adverse effect level (LOAEL) is 200 (172) mg/kg/day based on reduced maternal weight gain during gestation. The developmental NOAEL is 400 (340) mg/kg/day and the LOAEL was not determined. The potassium salt of picloram was administered to CD rats by gastric intubation at dosage levels of 0, 35 (30), 174 (150) and 347 (298) mg/kg/day during day 6-15 of gestation: The test vehicle was distilled water. There was no evidence of developmental toxicity at doses up to and including the high dose of 347 (298) mg/kg/day. The maternal LOAEL is 347 (298) mg/kg/day based upon excessive salivation in the dams of the high dose group. Hence, the developmental toxicity NOAEL is greater than or equal to 347 (298) mg/kg/day. The maternal toxicity LOAEL is 347 (298) mg/kg/day and NOAEL is 174 (150) mg/kg/day.

Picloram acid was evaluated in a 2-generation reproduction study in the CD rat. Dosage levels employed were 0, 20, 200 or 1,000 mg/kg/day. The parental LOAEL is 1,000 mg/kg/day based on histopathological lesions in the kidney of males of both generations and some females. In males of both generations, blood in the urine, decreased urine specific gravity, increased absolute and relative kidney weight, and increased body weight gain was observed at the high dose. The parental LOAEL is 1,000 mg/kg/day and the NOAEL is 200 mg/kg/day. The reproductive LOAEL was not identified and the NOAEL is 1,000 mg/kg/day.

4. *Subchronic toxicity*. In a 90 day oral toxicity study, picloram acid was administered via the diet to groups of 15 F344 rats/sex/dose at dosage levels of 0, 15, 50, 150, 300 or 500 mg/kg/day. Based upon liver weight changes and minimal microscopic changes in the liver, the systemic LOAEL is 150 mg/kg/day. The NOAEL is 50 mg/kg/day.

In a 1982 6 month dog dietary study, picloram acid was evaluated at dosage levels of 0, 7, 35 or 175 mg/kg/day. The systemic NOAEL is 35 mg/kg/day and the LOAEL is 175 mg/kg/day based on decreases in body weight gain and food consumption and increases in liver weights (relative), alkaline phosphatase and alanine transaminase. Increased liver to body weight ratios and absolute liver weights were observed in only two males at the 35 mg/kg/day dosage level.

In a 21 day dermal toxicity study, the potassium salt of picloram was administered dermally to groups of five New Zealand white rabbits of each sex at doses of 0 (vehicle control), 75.3, 251 or 753 mg/kg/day (0, 65, 217 or 650 mg/kg/day picloram acid equivalents) for a total of 15 applications over the 21 day period. The NOAEL is greater than or equal to 753 mg/kg/day for both sexes: hence, a LOAEL was not established for either sex. Although the limit dose of 1,000 mg/kg/day was not achieved, practical difficulties precluded administering more test material. The study revealed the non-systemic effects of dermal irritation and very slight to well defined edema and/or erythema in both sexes at all dose levels.

5. *Chronic toxicity*. In a 1988 1 year chronic feeding study in the dog, picloram acid was administered orally via the diet at dosage levels of 0, 7, 35 or 175 mg/kg/day The LOAEL is 175 mg/kg/day based on increased liver weight (absolute and relative). The NOAEL is 35 mg/kg/day.

In a chronic toxicity/carcinogenicity feeding study conducted in the F344 rat, picloram acid (technical grade 93 % containing 197 ppm hexachlorobenzene as an impurity) was evaluated at 0, 20, 60 or 200 mg/kg/day for 2 years. The chronic toxicity LOAEL was 60 mg/kg/day as evidenced by altered size, tinctorial properties of centrilobular hepatocytes, and increased absolute and/or relative liver weights in both sexes. The NOAEL was 20 mg/kg/day. The study was negative for carcinogenicity, but due to concerns that a MTD may not have been achieved and the fact that the test material contained 197 ppm hexachlorobenzene impurity, the study was not considered to fulfill adequately the carcinogenicity testing requirement.

In response to the deficiencies cited in the study above, an additional 2 year dietary chronic/carcinogenicity study was conducted (in 1992) using F344 rats administered picloram acid at dosage levels of 0, 250 or 500 mg/kg/day for 104 weeks. Chronic toxicity was observed at 250 mg/kg/day among males only (increased incidence and severity of glomerulonephritis, blood in urine, decreased specific gravity of urine, increased size of hepatocytes that often had altered staining properties). Among females there were chronic effects only at 500 mg/kg/day (increased glomerulonephropathy, increased absolute and relative kidney weight). There was no evidence of carcinogenicity in this study. It should be noted that use of the Osborne-Mendel rat was waived due to lack of availability of the strain of rat. In addition, the level of hexachlorobenzene in the test material employed in this study was 12 ppm. These two studies fulfill the guidelines 83-l(a) and 83-2(a) for rats.

In a 1992 2 year dietary carcinogenicity study in B6C3F1 mice, picloram acid was evaluated at doses of 0, 100, 500 or 1,000 mg/kg/day. The systemic NOAEL in this study is 500

mg/kg/day based on a significant increase in absolute and relative kidney weights in males at the high dose level (HDT). No histopathological lesions were found to corroborate these changes. There was no evidence of carcinogenicity.

The dose levels tested in the 1992 carcinogenicity studies in rats and mice were considered adequate for carcinogenicity testing. The treatment did not alter the spontaneous tumor profile in mice or different strains of rats tested under the testing conditions. The chemical was classified as a ''Group E - Evidence of Non-Carcinogenicity for humans''. This classification applies to the picloram acid and potassium salt forms for which acceptable carcinogenicity studies were available for review by the HED Carcinogenicity Peer Review Committee (May 26, 1988).

Using its Guidelines for Carcinogen Risk Assessment published September 24, 1986 (51 FR 33992), picloram is classified as Group ''E'' for carcinogenicity (no evidence of carcinogenicity) based on the results of the carcinogenicity studies. The dose levels tested in the 1992 carcinogenicity studies in rats and mice were considered adequate for carcinogenicity testing. The treatment did not alter the spontaneous tumor profile in mice or different strains of rats tested under the testing conditions. The chemical was classified as a ''Group E - Evidence of Non-Carcinogenicity for humans''. This classification applies to the picloram acid and potassium salt forms for which acceptable carcinogenicity studies were available for review by the HED Carcinogenicity Peer Review Committee (May 26, 1988). Thus, a cancer risk assessment would not be appropriate.

Hexachlorobenzene (HCB), a recognized impurity in picloram compounds, is considered to be an animal carcinogen and probable human carcinogen as discussed in the 1988 Registration Standard for picloram. The Q* is 1.02 (mg/kg/day)-1. The maximum level of HCB in picloram is considered to be 0.005%.

6. *Animal metabolism*. The absorption, distribution, metabolism and excretion of picloram acid was evaluated in female rats administered a single i.v. or oral gavage dose of 10 mg/kg, an oral gavage dose of 1,000 mg/kg ^{14}C-picloram, or 1 mg/kg/day unlabeled picloram by gavage for 14 days followed by a single oral gavage dose of 10 mg/kg ^{14}C-picloram on day 15. The study demonstrates that ^{14}C-picloram is rapidly absorbed, distributed and excreted following oral and i.v. administration. This study alone is not adequate; however, this study is acceptable when considered in conjunction with a male rat metabolism study which yielded similar results.

7. *Endocrine disruption*. An evaluation of the potential effects on the endocrine systems of mammals has not been determined; However, no evidence of such effects were reported in the chronic or reproductive toxicology studies described above. There was no observed pathology of the endocrine organs in these studies. There is no evidence at this time that picloram causes endocrine effects.

C. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

1. *Dietary exposure*—i. *Food*. For purposes of assessing the potential dietary exposure under these tolerances, aggregate exposure is estimated based on the theoretical maximum residue contribution (TMRC) from the existing and future potential tolerances for picloram on food crops. The TMRC is obtained by multiplying the tolerance level residues (existing and proposed) by the consumption data which estimates the amount of those food products eaten by various population subgroups. Exposure of humans to residues could also result if such residues are transferred to meat, milk, poultry or eggs. The following assumptions were used in conducting the HED exposure assessment 100% of the crops were treated, the RAC residues would be at the level of the tolerance, and some refinements were made based on marketing information previously supplied to HED by BEAD. This screening level analysis results in an overestimate of human exposure and a conservative assessment of risk. .

The chronic dietary exposure/risk estimates for picloram are extremely low. For the United States population as a whole, the TMRC is 0.0011 milligram kilogram body weight day (mg/kg/bwt/day), <1 of the RfD. The subgroup with the greatest routine chronic exposure is Non-nursing Infants (< 1 year old), which has a TMRC of 0.0042 mg/kg/bwt/day (2% of the RfD).

There is currently no form of sorghum observed in human consumption surveys utilized by EPA in their dietary risk evaluation system (DRES) assessments. Furthermore, residues of picloram in sorghum do not increase the dietary burden of picloram in animal feeds. Therefore, sorghum tolerances will have no effect on the human dietary consumption of picloram, and the proposed action, as well as existing tolerances, pose no concern with regards to chronic dietary exposure to food residues of picloram.

The estimated carcinogenic dietary risk for HCB as an impurity in picloram only for the U.S. population is 1.5 x10^{-7} which is less than the 1.0 x10^{-6} point below which risk is generally considered to be negligible.

ii. *Drinking water*. An additional potential source of dietary exposure to residues of pesticides are residues in drinking water. The Maximum Contaminant Level (MCL) for residues of picloram in drinking water has been established at 500 µg/L and a 1-10 day Health Advisory of 20,000 µg/L.

The Agency has published screening methods for estimating chemical residues in both ground water (SCI-GROW2) and surface water (GENEEC). Employing these methods yields the following 56 day Expected Environmental Concentrations (EEC) for a range of application rates:

Application rate (lb. acid equivalent/acre) and use	SCI-GROW2 EEC (µg/L)	GENEEC EEC (µg/L)
0.023 (wheat, barley, and oats use rate).	4.4	1.2
1 (maximum broadcast rate in label).	189	51.3
2 (maximum spot treatment rate in label).	379	103.1

The 56 day value is an appropriate endpoint to employ for the chronic exposure scenario. Default, conservative inputs were used for the models, as described in July 27, 1998 memorandum from EPA to Dow AgroSciences. Employing these values, a worst-case drinking water risk assessment can be performed as summarized below:

Population Subgroup[1]	RfD (mg/kg/day)	Food Exposure (mg/kg/day)	Maximum Water Exposure (mg/kg/day)[2]	DWLOC (μg/L)[3]	SCI-GROW2 EEC (μg/L)	GENEEC EEC (μg/L)
US Population	0.2	0.0011	0.2	7000	379	103.1
Females (13-19, not nursing or pregnant).	0.2	0.00090	0.2	6000	379	103.1
Non-Nursing infants (<< 1 yr. old).	0.2	0.0043	0.2	2000	379	103.1

[1] Population subgroups chosen in EPA memorandum of 7/27/98
[2] = RfD - ARC from DRES (cited above)
[3] Drinking water level of concern, based on default water body weights and water consumption of : 70 kg/2L (adult males), 60 kg/2L (adult female), 10 kg/1L (infant)

This tables shows that for even the most highly exposed population, exsure from water is below HED's DWLOC for chronic dietary exposure. Further refinement is also possible, based on monitoring data. Monitoring data available from the Pesticides in Ground Water Database indicate that picloram has been detected in ground water at concentrations ranging up to 30 μg/L. Results reported in this database typically were focused on highly vulnerable areas and in many cases, the database reports information from poorly constructed or damaged wells. These wells are at high risk because of the potential for surface residues to be carried directly down the casing into the ground water. Recognizing these high risk situations, an analysis of this database shows that less than 3% of the wells sampled were found to contain picloram. No distinction has been made between point and non point sources of material. Many of the detections are known to be related to point source contamination including spills at mixing/loading sites, near wells and back siphoning events. Of the detections which may have resulted from non-point sources, none are documented to occur on sites where application would be recommended based on current labeling. Nearly 99% of the ground water detections are at levels of less than 1% of the Maximum Contaminant Level (i.e., > 5 μg/L) established for human consumption by the EPA Office of Drinking Water. The STORET database maintained by the USEPA Office of Drinking Water indicates that picloram has been reported in surface water samples before 1988. Of these detections, 85% were at concentrations 0.13 μγ/L or lower and the maximum was 4.6 μγ/L. The maximum concentration reported was 4.6 μγ/L. Comparing these values to the DWLOC shows an even greater degree of protection for all of the population subgroups.

HCB contamination of ground water resources is relatively unlikely due to its high binding potential.

Based on monitoring data and fate properties it is unlikely that long term HCB concentrations in surface water would exceed 10 parts per trillion (ppt). Therefore, exposure from water is below EPA's drinking water level of concern of 34 ppt for chronic dietary exposure to HCB for the U.S. population.

In summary, these data on potential water exposure indicate insignificant additional dietary intake and risk for picloram.

2. *Non-dietary exposure*. This is a restricted use chemical that has no residential uses at this time; therefore, there are no human risks associated with residential uses. Entry into a treated area soon after the application of picloram is expected to be rare given the cultural practices typically associated with the use-sites (rights-of-way, forestry, pastures, range lands, and small grains) defined by the picloram labels at this time. Furthermore, if entry should occur, the potential exposures are expected to be minimal due to the characteristics of those use-sites

D. Cumulative Effects

Picloram is a pyridine carboxylic acid herbicide. Other herbicides in this class include clopyralid, quinclorac and thiazopyr. Section 408(b)(2)(D)(v) of the Food Quality Protection Act (FQPA) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity''. The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether picloram has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of these tolerance actions, therefore, EPA has not assumed that picloram has a

common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population*. In the meeting of September 30, 1993, the OPP RfD Peer Review Committee recommended that the RfD for this chemical be based on a NOAEL of 20 mg/kg/day for a dose-related increase in size and altered tinctorial properties of centrilobular hepatocytes in males and females at 60 and 200 mg/kg/day in a chronic toxicity study in rats. An uncertainty factor (UF) of 100 was used to account for the inter-species extrapolation and intra-species variability. On this basis, the RfD was calculated to be 0.20 mg/kg/day. The TMRC from existing tolerances is 0.001845 mg/kg/day. Existing tolerances utilize >1% of the RfD. It should be noted that no regulatory value has been established for this chemical by the World Health Organization (WHO) up to this date. The committee classified picloram as a ''Group E'' chemical, no evidence of carcinogenicity for humans.

Using the conservative exposure assumptions described above and based on the completeness and reliability of the toxicity data, it is concluded that aggregate exposure to picloram will utilize approximately 1% of the RfD for the U.S. population. Generally, exposures below 100% of the RfD are of no concern because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risk to human health. Thus, there is a reasonable certainty that no harm will result from aggregate exposure to picloram residues.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of picloram, data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat were considered. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism during prenatal development resulting from pesticide exposure to one or both parents. Reproduction studies provide (1) information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and (2) data on systemic toxicity.

Developmental toxicity was studied using rats and rabbits. The developmental study in rats resulted in a developmental NOAEL of >298 mg/kg/day and a maternal toxicity NOAEL of 280 mg/kg/day. A study in rabbits resulted in a maternal NOAEL of 34 mg/kg/day and a developmental NOAEL of 344 mg/kg/day. Based on all of the data for picloram, there is no evidence of developmental toxicity at dose levels that do not result in maternal toxicity.

In a 2-generation reproduction study in rats, The NOAEL for parental systemic toxicity is 200 mg/kg/day. There was no effect on reproductive parameters at 1,000 mg/kg/day nor was there an adverse effect on the morphology, growth or viability of the offspring; thus, the reproductive NOAEL is 1,000 mg/kg/day.

FDCA section 408 provides that EPA may apply an additional safety factor for infants and children in the case of threshold effects to account for pre- and post-natal toxicity and the completeness of the database. Based on the current toxicological data requirements, the database relative to pre- and post-natal effects for children is complete. Therefore, it is concluded that an additional uncertainty factor is not warranted and that the RfD at 0.2 mg/kg/day is appropriate for assessing aggregate risk to infants and children.

Using the conservative exposure assumption previously described, it is concluded that the percent of the RfD that will be utilized by aggregate exposure to residues of picloram will be less than 4% of the RfD for all populations and subgroups. Since this estimate represents the 'worst case' exposure for a given population (Non-nursing infants, >1 year old), exposures will be less for all other sub-populations e.g. children, 1-6 years. Therefore, based on the completeness and reliability of the toxicity data and the conservative exposure assessment, it is concluded that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to picloram residues.

F. International Tolerances

There are no Codex maximum residue levels established for residues of picloram.

G. Other Considerations

Data Gaps. Residue data for sorghum aspirated grain fractions is currently being generated. Based on the toxicological data and the levels of exposure, EPA has determined that the proposed tolerances will be safe.

[FR Doc. 98–31067 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–832; FRL–6027–6]

Notice of Filing of Pesticide Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–832, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Public Information and Records Integrity Branch (7502C), Information Resources and Services Division, Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Bipin Gandhi, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office Location, telephone number, and e-mail address: Rm. 707A, CM #2 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703–8380, e-mail: gandhi.bipin@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows

proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that these petitions contain data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–832] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket control number [PF–832] and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 22, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. EDM Corp

PP 8E4968

EPA has received a pesticide petition (8E4968) from EDM Corp 2278 So. Indiana Porterville, CA 93257 proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for Yucca Extract in or on the raw agricultural commodity when used in accordance with good agriculture practice as an inert ingredient in pesticide formulations applied to growing crops, the EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. No plant metabolism studies have been submitted in support of this tolerance exemption petition since yucca extract, a sarsasaponin is present in most plant life.

2. *Analytical method*. Since the petitioner has requested a tolerance exemption, a residue analytical method is not required.

3. *Magnitude of residues*. No yucca extract residue studies were conducted since yucca extract is naturally found at significant levels (> .68 ppm) in many different types of food. In addition, residue trials are not practical since it is very difficult to distinguish Sarsaponin residues naturally occurring versus sapsaponin residues from yucca extract.

B. Toxicological Profile

1. *Acute toxicity— Study #6176-P320 acute oral toxicity*. The acute oral LD^{50} for a 70% solution of yucca extract is > 5,000 milligrams/kilogram (mg/kg). Accordingly, yucca extract relatively non-toxic by the oral route.

The petitioner has requested that the Agency waive all sub-chronic, chronic/oncogenicity, mutagenicity, developmental and reproductive toxicity study requirements for yucca extract. There is an overwhelming lack of evidence for any chronic effects induced by dietary ingestion of yucca extract.

C. Aggregate Exposure

1. *Food*. The FDA title 21 under CFR 172.510, FEMA #3121, No Limitations. Food. Sarsasaponin is naturally found in several types of foods, such as fruits and vegetables,(asparagrus, legumes ect) at various levels.

2. *Drinking water*. Degradation of sarsasaponin in water.

D. Cumulative Effects.

No cumulative adverse effects are expected from long-term exposure to yucca extract.

E. Safety Determination

1. *U.S. population*. Yucca has been approved for uses in food and beverages by the FDA title 21 CFR 172.510, FEMA number 3121, with no limits. Approval of this petition will not increase dietary exposure to yucca extract. Accordingly, there is reasonable certainty that no harm will result from aggregate exposure of the U.S. population to yucca extract.

2. *Infants and children*. Since yucca extract is also an additive in soft drinks, root beer etc. the daily exposure to children is anticipated to be trivial, no adverse effects on infants or children are expected.

F. International Tolerances

There are no approved CODEX maximum residue levels (MRLS) established for residues of yucca extract.

Previously submitted Yucca extract data:

1. THERM-70 Study #6176-P320 Acute Oral Toxicity.

2. Regarding the use of the inert ingredient Yucca extract:

A-350 tons raw materials are used for all usese in the United States.

B- 300,000 lbs of raw material makes 4,630 gallons of THERMX-70 for pesticidal uses.

C- CELLU-CON, INC. Received raw material in 1997 from Mexico (85%) and U.S. 15%.

D- Yucca already approved for uses in food and beverages by the FDA title 21 CFR 172.510, FEMA number 3,121, no limits.

E- We would like to waive Yucca (Schidigera) to be approved under title 40 CFR in section 180.1001 as an Inert Ingredient.

3. This is to advise you regarding EDM's use of Yucca. We will not be using more than 6% THERMX-70 as a wetting in our product MIRAGE.

Enclosed is a packet of information to assist you in studying this material.

A- FDA 21 CFR 172.510
B- COMMERCIAL FEED LICENSE
C- THERMX-70 label
D- THERMX-70 MSDS sheet
E- Sarsaponin (Micro-Aid)

4. DESERT PRIDE label Yucca Herbal Food Tablets has been sold in stores since 1974.

2. Hercules, Incorporated

PP 6E4782

EPA has received a pesticide petition (PP 6E4782) from Hercules, Incorporated, 1313 North Market Street, Wilmington, Delaware, proposing pursuant to section 408(d) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 to establish an exemption from the requirement of a tolerance for polymers of α-pinene and/or *B*-pinene in or on raw agricultural commodities. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Toxicological Profile

1. *Acute toxicity.* An acute oral intubation test was conducted. Two male and two female rats were administered four dose levels of oligomeric copolymer ranging from 10.2 to 34.6 g/kg. No deaths resulted. The oral LD_{50} in rats is therefore >34.6 g/kg. An acute eye irritation study was conducted. Two rabbits were treated with 0.1 milliliter (ml) of undiluted oligomeric copolymer material instilled in each eye. One eye of each animal was rinsed with running water after one minute. The unwashed eye showed moderate irritation to the iris and conjunctiva which persisted for 4 days after treatment. Irritation in the washed eyes was mild and persisted for 3 days after treatment.

2. *Reproductive and developmental toxicity.* Petitioner has not identified a reproduction study in which the test substance was an α-pinene based polymer. In the interest of complete disclosure, Petitioner is aware of a limited reproduction study dated 1960 that was conducted at the LaWall & Harrisson Laboratories in connection with a larger 2-year feeding study. The test substance was Hercules Piccolyte S125 Polyterpene Resin, a *B*-pinene-based resin which is derived from the polymerization of a terpene feedstock containing a minimum *B*-pinene content of 80% and an α-pinene content of between 5% and 9%. Groups of six female Sprague-Dawley rats were fed the test substance at 0%, 3%, or 10% of the diet. After 4 months of exposure, the rats were mated with similarly treated males. All females bore litters except one from the untreated control group. All litters were normal in size and a few stillborn pups were noted in each group. There were some deaths among the pups, but survival to weaning was equal in all groups. Indices of reproductive and developmental performance were not calculated. The dietary level of 10% was considered the no-observed-adverse-effect level (NOAEL) in this limited reproduction study.

3. *Subchronic toxicity— i. Study No. 1.* In a study conducted in 1968, groups of 10 male and 10 female Charles River rats were fed diets containing 0%, 1%, 3%, or 5% of an α-pinene based resin for 3 months. Criteria of evaluation for possible toxic effects included general appearance and behavior, growth, food consumption, survival, clinical laboratory results, absolute and relative organ weights, and gross and microscopic pathology. Effects seen at the 5% dietary concentration include increases in relative liver weight in both sexes, and absolute liver weight in females only. Increased relative thyroid weight in males was noted at the 5% and 3% dosage levels. In the absence of histopathological alterations, these changes are regarded as adaptive and not of toxicological significance. The dietary level of 5%, equivalent to an overall average of 3,967 milligrams/kilogram/day (mg/kg/day) is considered the NOAEL in this study.

ii. *Study No. 2.* Groups of ten male and ten female Sprague-Dawley rats were fed diets containing 0%, 0% (i.e., two untreated controls), 0.01%, 0.05%, 0.2%, 1%, or 5% of Terpene AP for 90 days. Criteria of evaluation included appearance and behavior, growth, survival, hematology and urinalysis, organ weights and gross and microscopic pathological evaluation. A paired feeding study was conducted in conjunction with the main study to evaluate the significance of diet rejection vs. compound-related toxicity in weight gain reduction associated with high concentrations of Terpene AP. In the paired feeding study, each rat fed 5% Terpene AP (Test Group) was matched with a rat of the same sex and similar weight. Each of the Paired Feeding Control Group received the same amount of diet in each 24-hour period as the corresponding treated rat during the preceding reference 24-hour period, but without the test material. Two deaths occurred during the study. They were not dosage-related and were attributed to respiratory infection and not to compound-related toxicity. Decreased body weight gain and increased liver weight were consistent findings. Final body weights were reduced 16% in males and 11% in females at the highest dosage level. The paired-feeding study demonstrated that the effect was due to food rejection based on poor palatability and not due to systemic toxicity of the test material. Liver weight, as absolute weight and liver/brain weight ratios, increased in a dosage-related fashion. At the 5% dietary levels, 39% and 83% absolute weight increases were noted in males and females, respectively. Lesser increases were noted at the 1% and 0.2% dietary levels of the test material. Liver weight/body weight ratios were increased artifactually because of the growth depression. Since there were no adverse histological findings associated with the liver weight increases, the finding is attributed to generalized physiologic stress and not to organ-specific toxicity. Thyroid hyperplasia noted in some rats at the 5% and 1% levels is a secondary effect of the liver weight increase. The dietary concentration of 0.05% Polyterpene was a NOAEL in this 90-day study. Because food consumption was not evaluated, an equivalent mg/kg/day NOAEL could not be calculated in this study. Based on analyses of food consumption data from similar studies, an approximate dosage equivalent would be 37.5 mg/kg/day.

4. *Chronic toxicity—* i. *Study No. 3.* A terpene resin was fed to beagle dogs, three per sex per group, at dietary levels of 0%, 0.2%, 1% and 5% for 2 years. Criteria of effect included appearance and behavior, growth and survival, food consumption, hematology, clinical chemistry, urinalysis, absolute and relative organ weights and gross and microscopic pathology. Effects seen at the 5% dietary level included moderate reduction in growth and increased absolute and relative liver weight at 1 year and 2 years, and minimal hepatocellular fatty changes at 1 year but not 2 years. Similar liver effects were seen at the 1% dietary concentration. The dietary levels of 0.2% terpene resin equivalent to an overall average of 51 mg/kg/day, a NOAEL in this 2-year study.

ii. *Study No. 4.* Groups of 30 male and 30 female Sprague Dawley rats were fed diets containing 0%, 0.2%, 1%, or 5% terpene resin for 2 years. The terpene resin was a copolymer of α- and *B*-pinene. No differences from controls were noted in any test groups with respect to appearance and behavior,

food consumption, growth, survival, tumor incidence, hematology and urinalysis. All means were within the range of normal variation. Significant elevations of absolute and relative liver weight were noted in females after 12 months on the 1% and 5% diets. In males, absolute liver weight was elevated at the 5% level and relative liver weights were elevated at both the 1% and 5% levels. After 24 months of treatment, relative liver weights were elevated in males at 5% and in females at 1% and 5%. Histological examinations after 2 years showed only effects anticipated in untreated animals. Liver enlargement in the absence of histopathological changes results from compensatory effects. The highest dietary concentration of 5% terpene resin, equivalent to an overall average of 3,100 mg/kg body weight per day, is regarded as the NOAEL in this study.

5. *Endocrine disruption*. A comprehensive literature search has revealed no reports associating pinene monomers or polymers with endocrine effects. Petitioner has not undertaken any testing to explore further the possibility that pinene polymers or monomers could cause endocrine effects and understands that EPA will implement a screening program for endocrine effects in the future.

C. Aggregate Exposure

1. *Dietary exposure*. Synthetic terpene resin, consisting of polymers of α-pinene, *B*-pinene, and/or dipentene, is currently cleared by the Food and Drug Administration for use as an ingredient of chewing gum base and for use in a variety of food-contact or food packaging applications. The range of materials that are used in these applications under the name ''synthetic terpene resin'' will vary in composition and molecular weight. These existing food applications result in some small amount of dietary exposure to pinene monomers, oligomers, and polymers. This exposure can be expected to be quite small given that only a small amount, if any, of the synthetic terpene resin present in a food-contact article will migrate into food. Similarly, the insoluble gum base portion of chewing gum is ordinarily discarded after chewing, and like the other components of gum base, synthetic terpene resin is not extracted to any significant degree by saliva. Petitioner has presented calculations showing very roughly that even if the total annual U.S. production volume of terpene resins were incorporated directly into the diet, this would result in a per capita consumption of α-pinene and α-pinene repeating units of only 1.7 mg/kg body weight per day for a 60-kg adult. Actual intake will be significantly less than this number, given that not all synthetic terpene resin is used in food applications, and that very little migration and ingestion can be attributed to the existing food-contact and chewing gum applications.

2. *Food*. Petitioner does not manufacture sticker formulations and therefore has not conducted studies to show the actual quantity of pinene polymers that will remain on harvested food crops. Based on the conservative assumption that all pinene polymer will remain on food crops at the time of harvest, Petitioner has presented calculations showing that the resulting dietary exposure will not exceed 0.43 mg/kg body weight per day for a 60-kg adult. Actual intake will be less than his number. Petitioner notes that this intake is a subset of the worst-case aggregate exposure number, 1.7 mg/kg body weight per day.

3. *Drinking water*. Due to its relative insolubility, only trace amounts of pinene polymer, if any, will be found in drinking water. Some amount of pinene polymer will enter the soil in fields where it is applied as part of a pesticide formulation. Any pinene polymer present in the soil could potentially reach ground water, as is the case with agricultural chemicals generally. In the case of pinene polymers, Petitioner notes that they can be expected to adhere to the soil due to their adhesive properties and that they may biodegrade before reaching ground water. Petitioner further notes that any drinking water exposure will be within the worst-case aggregate exposure estimate, 1.7 mg/kg body weight per day.

4. *Non-dietary exposure*. Outside of food applications, pinene polymers are used in various adhesive applications including construction adhesives used, for example, to lay floor tile. Pinene polymers present in adhesives are not volatile and will therefore not be inhaled. The only human exposure will be that associated with accidental skin contact. It would be difficult to assign a numerical value to this non-occupational exposure for a typical person. Exposures from all sources cannot exceed 1.7 mg/kg body weight per day for a typical adult, given the total production volume of α-pinene polymers.

D. Cumulative Effects

No identified risks are associated with exposure to pinene polymers. The mechanism or mode of action associated with pinene polymers is simply that the substance is physically sticky.

E. Safety Determination

1. *U.S. population*. Petitioner estimates that exposure to α-pinene polymers and repeating units attributable to the requested action will be less than 0.43 mg/kg body weight per day in a 60-kg adult. This number is based on a set of conservative assumptions, and actual exposure is expected to be much less. In no event will aggregate exposure, by all routes and from all sources, exceed 1.7 mg/kg body weight, given the total production volume of α-pinene polymers. In several of the available animal feeding studies, the NOAEL was found to be 5% or more of the diet (greater than 3,000 mg/kg body weight per day). The lowest reported NOAEL of which the petitioner is aware is 37.5 mg/kg body weight, which is somewhat of an outlying value.

2. *Infants and children*. Infants and children will not experience higher levels of exposure to pinene polymers than the rest of the population as a result of the action requested in this petition. Furthermore, no chronic or acute effects are associated with pinene polymers, for which infants and children could be particularly sensitive. Petitioner expects pesticide sticker formulations containing pinene polymers to be used on a variety of food crops, which will lead to low levels of residues distributed evenly throughout the food supply. Considering this variety of uses, exposure should be spread evenly over the entire population and not concentrated in any particular sub-population. Dietary exposure in adults will not exceed 0.43 mg/kg body weight per day from the requested application, and aggregate exposure from all sources and routes cannot exceed 1.7 mg/kg body weight per day. These estimates correspond to an adult weighing 60 kg and consuming 1,500 grams of solid food per day. The numbers can be adjusted to account for the weight of a child. For example a child weighing 30 kg and consuming 1,000 g of solid food per day will be exposed to no more than 0.56 mg/kg body weight per day from the requested application and no more than an aggregate of 3.3 mg/kg body weight per day from all routes and all sources. Exposure estimates thus adjusted for children compare favorably with the NOAEL reported in the animal feeding studies.

[FR Doc. 98–31063 Filed 11–19–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

[PF–842; FRL–6042–1]

Notice of Filing of Pesticide Tolerance Petitions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain pesticide chemicals in or on various food commodities.

DATES: Comments, identified by the docket control number PF–842, must be received on or before December 21, 1998.

ADDRESSES: By mail submit written comments to: Information and Records Integrity Branch, Public Information and Services Divison (7502C), Office of Pesticides Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person bring comments to: Rm. 119, CM #2, 1921 Jefferson Davis Highway, Arlington, VA.

Comments and data may also be submitted electronically by following the instructions under ''SUPPLEMENTARY INFORMATION.'' No confidential business information should be submitted through e-mail.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as ''Confidential Business Information'' (CBI). CBI should not be submitted through e-mail. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. All written comments will be available for public inspection in Rm. 119 at the address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: Mary L. Waller, Registration Support Branch, Registration Division (7505W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 247, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703) 308–9354; e-mail: waller.mary@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA has received pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

The official record for this notice of filing, as well as the public version, has been established for this notice of filing under docket control number [PF–842] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official record is located at the address in ''ADDRESSES'' at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 file format or ASCII file format. All comments and data in electronic form must be identified by the docket control number (PF–842) and appropriate petition number. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

List of Subjects

Environmental protection, Agricultural commodities, Food additives, Feed additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 10, 1998.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them in any way. The petition summaries announce the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

1. Novartis Crop Protection, Inc.

PP 8F3654 PP 8F3674

EPA has received two pesticide petitions (PP 8F3654 & PP 8F3674) from Novartis Crop Protection, Inc., P.O. Box 18300, Greensboro, NC 27419, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing tolerances for residues of propiconazole (1-[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl]methyl-1H-1,2,4-triazole) in or on the raw agricultural commodities corn, fodder (12.0 parts per million (ppm)); corn, forage (12.0 ppm); corn, grain (0.1 ppm); corn, sweet (0.1 ppm); pineapples (0.1 ppm); pineapples, fodder (0.1 ppm) (PP 8F3674); peanuts (0.2 ppm); peanuts, hay (20 ppm); and peanuts, hulls (1.0 ppm) (PP 8F3654). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant/animal metabolism*. Novartis believes the studies supporting propiconazole adequately characterize metabolism in plants and animals. The metabolism profile supports the use of an analytical enforcement method that accounts for combined residues of propiconazole and its metabolites which contain the 2,4-dichlorobenzoic acid (DCBA) moiety.

2. *Analytical method*. Novartis has submitted a practical analytical method involving extraction, filtration, conversion, partition, derivitization, and solid phase cleanup with analysis by confirmatory gas chromatography using electron capture detection (ECD). The total residue method is used for determination of propiconazole and its metabolites. The limit of quantitation (LOQ) for the method is 0.05 ppm.

3. *Magnitude of residues*. Field residue trials have been conducted at various rates, timing intervals, and applications methods to represent the use patterns which would most likely

result in the highest residues. For all samples, the total residue method was used for determination of the combined residues of parent and its metabolites which contain the DCBA moiety.

B. Toxicological Profile

1. *Acute toxicity—Propiconazole exhibits low toxicity*. Data indicated the following: a rat acute oral LD_{50} of 1,517 milligrams/kilograms (mg/kg); a rabbit acute dermal LD_{50} > 6,000 mg/kg; a rat inhalation LC_{50} > 5.8 mg/liter air; minimal skin and slight eye irritation; and nonsensitization.

2. *Genotoxicty*. Propiconazole exhibits no mutagenic potential based on the following data: *In vitro* gene mutation test (Ames assay, rat hepatocyte DNA repair test, (human fibroblast DNA repair test), *In vitro* chromosome test, (human lymphocyte cytogenetic test), *In vivo* mutagenicity test, (Chinese hamster bone marrow cell nucleus anomaly test, Chinese hamster bone marrow cell micronucleus test, mouse dominant lethal test), and other mutagenicity test (BALB/3T3 cell transformation assay).

3. *Reproductive and developmental toxicity*. In an oral teratology study in the rabbit, a maternal no observed adverse effect level (NOAEL) of 30 mg/kg was based on reduced food intake but without any fetotoxicity even at the top dose of 180 mg/kg. In an oral teratology study in the rabbit, a maternal NOAEL of 100 mg/kg was based on reductions in body weight gain and food consumption and a fetal NOAEL of 250 mg/kg was based on increased skeletal variations at 400 mg/kg. In an oral teratology study in the rat, a maternal and fetal NOAEL of 100 mg/kg was based on decreased survival, body weight gain, and food consumption in the dams and delayed ossification in the fetuses at 300 mg/kg. In a second teratology study in the rat, a maternal and fetal NOAEL of 30 mg/kg was based on reductions in body weight gain and food consumption in the dams and delayed development in the fetuses at 90 and 360/300 mg/kg. A supplemental teratology study in the rat involving eight times as many animals per group as usually required showed no teratogenic potential for the compound. A 2-generation reproduction study in the rat showed excessive toxicity at 5,000 ppm without any teratogenic effects. A 2-generation reproduction study in the rat showed no effects on reproductive or fetal parameters at any dose level. Postnatal growth and survival were affected at the top dose of 2,500 ppm, and parental toxicity was also evident. The NOAEL for development toxicity is 500 ppm.

4. *Subchronic toxicity*. In a 21 day dermal study in the rabbit, a NOAEL of 200 mg/kg was based on clinical signs of systemic toxicity. In a 28 day oral toxicity study in the rat, a NOAEL of 50 mg/kg was based on increased liver weight. In a subchronic feeding study in the mouse, a NOAEL of 20 ppm (3 mg/kg) was based on liver pathologic changes. In a 13 week feeding study in the male mouse, a NOAEL of 20 ppm (3 mg/kg) was based on liver pathologic changes. In a 90 day feeding study in rats, the NOAEL was 240 ppm (24 mg/kg) based on a reduction in body weight gain. In a 90 day feeding study in dogs, the NOAEL was 250 ppm (6.25 mg/kg) based on reduced food intake and stomach histologic changes.

5. *Chronic toxicity*. In a 12 month feeding study in the dog, a NOAEL of 50 ppm (1.25 mg/kg) was based on stomach histologic changes. In a 24 month oncogenicity feeding study in the mouse, the NOAEL was 100 ppm (15 mg/kg). The MTD was exceeded at 2,500 ppm in males based on decreased survival and body weight. Increased incidence of liver tumor was seen in these males but no evidence of carcinogenicity was seen at the next lower dose of 500 ppm in either sex. In a 24 month chronic feeding/oncogenicity study in the rat, a NOAEL of 100 ppm (5 mg/kg) was based on body weight and blood chemistry. The MTD was 2,500 ppm based on reduction in body weight gain and no evidence of oncogenicity was seen. Based on the available chronic toxicity data, Novartis believes the Reference dose (RfD) for propiconazole is 0.0125 mg/kg/day. This RfD is based on a 1 year feeding study in dogs with a NOAEL of 1.25 mg/kg/day (50 ppm) and an uncertainly factor of 100. No additional modifying factor for the nature of effects was judged to be necessary as stomach mucosa hyperemia was the most sensitive indicator of toxicity in that study.

Using the Guidelines for Carcinogenic Risk Assessment published on September 24, 1986 (51 FR 33992), the USEPA has classified propiconazole in group C for carcinogenicity (evidence of possible carcinogenicity for humans). The compound was tested in 24 month studies with both rats and mice. The only evidence of carcinogenicity was an increase in liver tumor incidence in male mice at a dose level that exceeded the maximum tolerated dose (MTD). Dosage levels in the rat study were appropriate for identifying a cancer risk. The Cancer Peer Review Committee recommended the RfD approach for quantitation of human risk. Therefore, the RfD is deemed protective of all chronic human health effects, including cancer.

C. Aggregate Exposure

1. *Dietary exposure*. The RfD for propiconazole is 0.0125 mg/kg/day and is based on a 1 year feeding study in dogs with a NOAEL of 1.25 mg/kg/day (50 ppm) and an uncertainly factor of 100.

2. *Food*—i. *Acute risk*. The risk from acute dietary exposure to propiconazole is considered to be very low. The lowest NOAEL in a short term exposure scenario, identified as 30 mg/kg in the rat teratology study, is 24-fold higher than the chronic NOAEL. Based on worst-case assumptions, the chronic exposure assessment did not result in any margin of exposure (MOE) less than 150 for even the most impacted population subgroup. Novartis believes that the MOE for acute exposure would be more than 100 for any population groups; MOE of 100 or more are considered satisfactory.

ii. *Chronic risk*. For the purposes of assessing the potential dietary exposure under the existing, pending, and proposed tolerances for the residue of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid, Novartis has estimated aggregate exposure based upon the Theoretical Maximum Residue Concentration (TMRC). The TMRC is a ''worst case'' estimate of dietary exposure since it assumes 100% of all crops for which tolerances are established are treated and that pesticide residues are at the tolerance levels, resulting in an overestimate of human exposure.

Currently established tolerances range from 0.05 ppm in milk to 60 ppm in grass seed screenings and include: apricots (1.0 ppm); bananas (0.2 ppm); barley grain (0.1 ppm); barley straw (1.5 ppm); cattle kidney and liver (2.0 ppm); cattle meat, fat, and meat by products except kidney and liver (0.1 ppm); celery (5.0 ppm); corn forage and fodder (12.0 ppm); corn grain and sweet (0.1); eggs (0.1 ppm); goat kidney and liver (2.0 ppm); goat meat, fat, and meat by products except kidney and liver (0.1 ppm); grass forage (0.5 ppm); grass hay/straw (40.0 ppm); grass seed screenings (60.0 ppm); hogs kidney and liver (2.0 ppm); hog meat, fat, and meat by products except kidney and liver (0.1 ppm); horses kidney and liver (2.0 ppm); horse meat, fat, and meat by products except kidney and liver (0.1 ppm); milk (0.05 ppm); mint tops (0.3 ppm - regional tolerance west of Cascade Mountains); mushrooms (0.1 ppm); nectarines (1.0 ppm); oat forage (10.0 ppm); oat grain (0.1 ppm); oat hay (30.0 ppm); oat straw (1.0 ppm); peaches

(1.0 ppm); peanut hay (20.0 ppm); peanut hulls (1.0 ppm); peanuts (0.2 ppm);, pecans (0.1 ppm); pineapple (0.1 ppm); pineapple fodder (0.1 ppm); plums (1.0 ppm); poultry liver and kidney (0.2 ppm); poultry meat, fat, and meat by products except kidney and liver (0.1 ppm); prunes, fresh (1.0 ppm); rice grain (0.1 ppm); rice straw (3.0 ppm); wild rice (0.5 ppm regional tolerance Minnesota); rye grain (0.1 ppm); rye straw (1.5 ppm); sheep kidney and liver (2.0 ppm); sheep meat, fat, and meat by products except kidney and liver (0.1 ppm); stone fruit crop group 12 (1.0 ppm); wheat grain (0.1 ppm); and wheat straw (1.5 ppm). In addition, time-limited regional tolerances for sorghum grain and stover at 0.1 ppm and 1.5 ppm, respectively were established to support a Section 18 Crisis exemption in Texas (expiration date October 31, 1998).

Additional uses of propiconazole have been requested in several pending petitions. Proposed tolerances include: PP 5F4424 for use of propiconazole on drybean and soybean - dry bean forage (8.0 ppm); dry bean hay (8.0 ppm); dry bean vines (0.5 ppm); dry bean (0.5 ppm), soybeans (0.5 ppm); soybean fodder (8.0 ppm); soybean forage (8.0 ppm); soybean hay (25.0 ppm); and soybean straw (0.1 ppm). PP 5F4591 for use of propiconazole on berries, carrots and onions - berry crop grouping (1.0 ppm); dry bulb onion (0.3 ppm); green onion (8.0); PP 5F3740 - tree nut crop grouping (0.1 ppm); PP 5F4498 - inadvertent/rotational crop tolerances for alfalfa forage (0.1 ppm), alfalfa hay (0.1 ppm), grain sorghum fodder (0.3 ppm), grain sorghum forage (0.3 ppm) and grain sorghum grain (0.2 ppm).

3. *Drinking water*. Other potential sources of exposure of the general population to residues of propiconazole are residues in drinking water and exposure from non-occupational sources. Review of environmental fate data by the Environmental Fate and Effects Division of USEPA indicates that propiconazole is persistent and moderately mobile to relatively immobile in most soil and aqueous environments. No Maximum Concentration Level (MCL) currently exists for residues of propiconazole in drinking water and no drinking water health advisory levels have been established for propiconazole.

The degradation of propiconazole is microbially mediated with an aerobic soil metabolism half-life of 70 days. While propiconazole is hydrolytically and photochemically stable ($T_{1/2}$ >100 days), it binds very rapidly and tightly to soil particles following application. Adsorption/desorption and aged leaching data indicate that propiconazole and its degradates will primarily remain in the top 0-6 inches of the soil. It has been determined that under field conditions propiconazole will degrade with a half-life of approximately 100 days.

4. *Non-dietary exposure*. Propiconazole is registered for residential use as a preservative treatment for wood and for lawn and ornamental uses. At this time, no reliable data exist which would allow quantitative incorporation of risk from these uses into a human health risk assessment. The exposure to propiconazole from contacting treated wood products is anticipated to be very low since the surface of wood is usually coated with paint or sealant when used in or around the house. The non-occupational exposure from lawn and ornamental applications is also considered to be minor. It is estimated that less than 0.01% of all households nationally use propiconazole in a residential setting.

D. Cumulative Effects

Consideration of a common mechanism of toxicity is not appropriate at this time since there is no reliable information to indicate that toxic effects produced by propiconazole would be cumulative with those of any other types of chemicals. While other triazoles are available on the commercial or consumer market, sufficient structural differences exist among these compounds to preclude any categorical grouping for cumulative toxicity. Consequently, Novartis is considering only the potential risks of propiconazole in its aggregate exposure assessment.

E. Safety Determination

1. *U.S. population—Reference dose*. Using the conservative exposure assumptions described above (100% stone fruit acres treated and tolerance level residues) and based on the completeness and reliability of the toxicity data base for propiconazole, Novartis has calculated aggregate exposure levels for this chemical. The calculation shows that only 16% of the RfD will be utilized for the U.S. population based on chronic toxicity endpoints. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Novartis concludes that there is a reasonable certainty that no harm will result from aggregate exposure to propiconazole residues.

2. *Infants and children*. Developmental toxicity (e.g., reduced pup weight and ossification) was observed in the rat teratology studies and 2-generation rat reproduction studies at maternally toxic doses. Some of these findings are judged to be nonspecific, secondary effects of maternal toxicity. The lowest NOAEL for developmental toxicity was established in the rat teratology study at 30 mg/kg, a level 24-fold higher than the NOAEL of 1.25 mg/kg on which the RfD is based.

3. *Reference dose*. Using the same conservative exposure assumptions as employed for the determination in the general population, Novartis has calculated that the percent of the RfD that will be utilized by aggregate exposure to residues of propiconazole is 26% for nursing infants less than 1 year old, 65% for non-nursing infants less than 1 year old, 35% for children 1-6 years old, and 23% for children 7-12 years old. Therefore, based on the completeness and reliability of the toxicity data base and the conservative exposure assessment, Novartis concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to propiconazole residues.

F. International Tolerances

International CODEX values are established for almond, animal products, bananas, barley, coffee, eggs, grapes, mango, meat, milk, oat, peanut-whole, peanut grains, pecans, rape, rye, stone fruit, sugar cane, sugar beets, sugar beet tops, and wheat. The U.S. residue definition includes both propiconazole and metabolites determined as 2,4-dichlorobenzoic acid (DCBA), while the CODEX definition is for propiconazole, per se, i.e. parent only. This difference results in unique tolerance expressions with the U.S. definition resulting in the higher tolerance levels.

2. Tomen Agro, Inc. and Bayer Corporation, Agriculture Division

PP 7F4890

EPA has received a pesticide petition (PP 7F4890) from the TM-402 Fungicide Task Force comprised of Tomen Agro, Inc., 100 First Street, Suite 1610, San Francisco, CA 94105 and Bayer Corporation, Agriculture Division, 8400 Hawthorn Road, P.O. Box 4913, Kansas City, MO 64120-0013, proposing pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of N-(2,3-dichloro-4-hydroxyphenyl)-1-

methyl-cyclohexanecarboxamide (TM-402 or Fenhexamid) in or on the raw agricultural commodities grapes and strawberries at 3.0 parts per million (ppm) and in raisens at 6.0 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Analytical method*. An adequate method for purposes of enforcement of the proposed TM-402 tolerances in plant commodities is available. Bayer AG Analytical Method No. 00362 was used by Bayer AG to determine magnitude of TM-402 residues in fresh and processed grapes. This method has been independently validated. The limits of quantitation (LOQ) were determined to be 0.02 ppm for grapes, wine, and juice, and 0.05 ppm for strawberries, and raisins.

2. *Magnitude of residues*. The maximum TM-402 residues in fresh grapes, grape juice, raisins or wine permitted by the proposed label is 2.9 ppm. The maximum TM-402 calculated residue for grape juice is 1.7 ppm. For raisins the calculated residue value is 5.2 ppm, and for wine the value is 1.2 ppm. The maximum TM-402 residue for fresh strawberries permitted by the proposed label is 2.3 ppm. The average TM-402 residues for fresh grapes, grape juice, raisins and wine resulting from the treatment of grapes permitted by the proposed label are 1.3 ppm. The average TM-402 calculated residue for grape juice is 0.8 ppm. For raisins the average calculated residue value was 2.3 ppm, and for wine the values are 0.52 ppm. The average TM-402 residue for fresh strawberries permitted by the proposed label is 1.2 ppm. Since strawberries, grapes and processed grape commodities are not significant livestock feeds, a nature-of-the-residue discussion in livestock is not required. Additionally, since no aquatic uses are proposed, magnitude of the residue data in fish and irrigated crops are not required.

B. Toxicological Profile

1. *Acute toxicity*. Data from a complete battery of acute toxicity studies for TM-402 technical are available. The acute oral toxicity study resulted in an LD_{50} of >5,000 milligrams/kilogram (mg/kg) for both sexes. The acute dermal toxicity in rats resulted in an LD_{50} of > 5,000 mg/kg for both sexes. The acute inhalation was investigated in two studies in rats. Inhalation by aerosol at the maximum technically possible concentration of 0.322 mg/l resulted in no deaths or symptoms (LC_{50} >0.322 mg/l). A dust inhalation study resulted in an LC_{50} >5.057 mg/l. TM-402 was not irritating to the skin or eyes after a 4 hour exposure period. The Buehler dermal sensitization study in guinea pigs indicated that TM-402 is not a sensitizer. Based on these results TM-402 technical is placed in toxicity Category IV and does not pose any acute dietary risks.

2. *Genotoxicty*. The potential for genetic toxicity of TM-402 was evaluated in six assays including two Ames tests, an HGPRT forward mutation assay, a UDS assay, an *in vitro* chromosomal aberration assay in CHO cells, and a micronucleus test in mice. The compound was found to be devoid of any mutagenic activity in each of these assays including those tests that investigated the absence or presence of metabolic activating systems. The weight of evidence indicates that TM-402 technical does not pose a risk of mutagenicity or genotoxicity.

3. *Reproductive and developmental toxicity*. TM-402 has been tested for reproductive toxicity in rats and developmental toxicity in both rats and rabbits.

i. In a 2-generation reproduction study (one mating per generation), 30 Sprague-Dawley rats per sex per dose were administered 0, 100, 500, 5,000, or 20,000 ppm of TM-402 in the diet. The reproductive toxicity no observed adverse effect level (NOAEL) was 20,000 ppm. The neonatal NOAEL was 500 ppm, and the lowest observed effect level (LOAEL) was 5,000 ppm based on decreased pup body weight. The parental toxicity NOAEL was 500 ppm based on lower adult pre-mating body weights at 5,000 and 20,000 ppm, lower gestation body weights at 20,000 ppm, lower lactation body weights at 5,000 and 20,000 ppm, and statistically significant changes in clinical chemistry parameters, terminal body weights, and organ weights at 5,000 and 20,000 ppm. Based on this study, it is clear that the only toxic effects in the neonates occurred at parentally toxic doses.

ii. *In rats*. TM-402 was administered by gavage at doses of 0 or 1,000 mg/kg for gestation days 6-15. No maternal toxicity, embryotoxicity, fetotoxicity, or teratogenic effects were observed at the limit dose of 1,000 mg/kg/day. Therefore, the NOAEL for maternal and developmental toxicity was 1,000 mg/kg/day.

iii. *In rabbits*. TM-402 was administered by gavage at doses of 0, 100, 300, and 1,000 mg/kg for gestation days 6-18. Body weight gain and feed consumption of the dams were reduced at the two top doses. One abortion occurred in each of the top two dose groups and two total resorptions occurred in the top dose group. The placental weights were slightly decreased at 300 mg/kg/day and above. In the 1,000 mg/kg/day group slightly decreased fetal weights and a slightly retarded skeletal ossification were observed. All other parameters investigated in the study were unaffected. Therefore, the NOAELs for maternal and developmental toxicity were 100 mg/kg/day in this study.

Based on the 2-generation reproduction study in rats, TM-402 is not considered a reproductive toxicant and shows no evidence of endocrine effects. The data from the developmental toxicity studies on TM-402 show no evidence of a potential for developmental effects (malformations or variations) at doses that are not maternally toxic. The NOAEL for both maternal and developmental toxicity in rats was 1,000 mg/kg/day and for rabbits the NOAEL for both maternal and developmental toxicity was 100 mg/kg/day.

4. *Subchronic toxicity*. The subchronic toxicity of TM-402 has been evaluated in rats, mice, and dogs.

i. TM-402 was administered in the diet to rats for 13 weeks at doses of 0, 2,500, 5,000, 10,000 and 20,000 ppm. The NOAEL was 5,000 ppm (415 mg/kg/day in males and 549 mg/kg/day in females). Reversible liver effects were observed at 10,000 ppm.

ii. TM-402 was administered in the diet to mice for approximately 14 weeks at doses of 0, 100, 1,000 and 10,000 ppm. The NOAEL was 1,000 ppm (266.6 mg/kg/day in males and 453.9 mg/kg/day in females). Increased feed and water consumption and kidney and liver effects were observed at 10,000 ppm.

iii. TM-402 was administered in the diet to beagle dogs for 13 weeks at doses of 0, 1,000, 7,000 and 50,000 ppm. The NOAEL was 1,000 ppm (33.9 mg/kg/day in males and 37.0 mg/kg/day in females. Increased Heinz bodies were observed at 7,000 ppm.

5. *Chronic toxicity*. The chronic toxicity of TM-402 has been evaluated in a 1 year dog study and a 2 year chronic toxicity/oncogenicity study in rats.

i. TM-402 was administered in the feed at doses of 0, 500, 3,500, or 25,000 ppm to 4 male and 4 female beagle dogs per group for 52 weeks. A systemic

NOAEL of 500 ppm (an average dose of 17.4 mg/kg/day over the course of the study) was observed based on decreased food consumption and decreased body weight gain at 25,000 ppm, decreased erythrocyte, hemoglobin and hematocrit values at 25,000 ppm, increased Heinz bodies at 3,500 ppm and above, and a dose-dependent increase of alkaline phosphatase at 3,500 ppm and above. There were no treatment related effects on either macroscopic or histologic pathology.

ii. A combined chronic/oncogenicity study was performed in Wistar rats. Fifty animals/sex/dose were administered doses of 0, 500, 5,000, or 20,000 ppm for 24 months in the feed. A further 10 animals/sex/group received the same doses and were sacrificed after 52 weeks. The doses administered relative to body weight were 0, 28, 292, or 1,280 mg/kg/day for males and 0, 40, 415, or 2067 mg/kg/day for females. The NOAEL in the study was 500 ppm (28 mg/kg/day for males and 40 mg/kg/day for females) based on body weight decreases in females at 5,000 ppm and above, changes in biochemical liver parameters in the absence of morphological changes in both sexes at 5,000 ppm and above, and caecal mucosal hyperplasia evident at 5,000 ppm and above.

The NOAEL in the chronic dog study was 17.4 mg/kg/day based on body weight, hematology and clinical chemistry effects. The lowest NOAEL in the 2 year rat study was determined to be 28 mg/kg/day based on body weight, clinical chemistry parameters in the liver, and caecal mucosal hyperplasia.

6. *Oncogenicity*. The oncogenic potential of TM-402 has been in a 2 year oncogenicity study in mice and a 2 year chronic toxicity/oncogenicity study in rats.

i. *Mouse*. TM-402 was administered to 50 B6C3F1 mice/sex/group in their feed at concentrations of 0, 800 ,2,400 , or 7,000 ppm for 24 months. These concentrations resulted in a compound intake of 247.4,807.4 or 2354.8 mg,kg,day in males and 364.5, 1054.5 and 3178.2 mg/kg/day in females. A further 10 mice/sex/group received the same concentrations and were sacrificed after 12 months. There was no treatment effect on mortality, feed consumption,the hematological system or on the liver. Water consumption was increased in both sexes, and body weights were 8% lower in males at the highest dose of 7,000 ppm. At 7,000 ppm, elevated plasma creatinine concentrations, decreased kidney weights, and an increased occurrence of morphological lesions indicated a nephrotoxic effect of the compound. There was no shift in the tumor spectrum with treatment, and therefore, TM-402 was not oncogenic in this study.

ii. *Rat*. In the 2 year rat chronic/oncogenicity study described above, there was no indication of an oncogenic response. There was no indication of an oncogenic response in the 2 year rat and mouse studies on TM-402.

7. *Neurotoxicity*. The possibility for acute neurotoxicity of TM-402 was investigated. TM-402 was administered by gavage ina single dose to 12 Wistar rats/sex/group at doses of 0, 200, 630, 2,000 mg/kg. There was no evidence of neurotoxicity at any level tested.

8. *Endocrine disruption*. TM-402 has no endocrine-modulation characteristics as demonstrated by the lack of endocrine effects in developmental, reproductive, subchronic, and chronic studies.

C. Aggregate Exposure

1. *Dietary exposure*. Sources of dietary exposure to TM-402 are limited to the crops in the current submission. The following are the proposed tolerances: grapes - 3.0 ppm and strawberries - 3.0 ppm. A food additive tolerance of 6.0 ppm in raisins is also being proposed.

2. *Drinking water*. Review of the environmental fate data indicates the TM-402 is relatively immobile and rapidly degrades in the soil and water. TM-402 dissipates in the environment via several processes. Therefore, a significant contribution to aggregate risk from drinking water is unlikely.

3. *Non-dietary exposure*. There is no significant potential for non-occupational exposure to the general public. The proposed uses are limited to agricultural and horticultural use.

D. Cumulative Effects

Consideration of a common mechanism of toxicity is not appropriate at this time since there is no significant toxicity observed for TM-402. Even at toxicology limit doses, only minimal toxicity is observed for TM-402. Therefore, only the potential risks of TM-402 are considered in the exposure assessment.

E. Safety Determination

1. *U.S. population*. Based on the most sensitive species, Tomen Agro has calculated an appropriate Reference Dose (RfD) for TM-402. Using the NOAEL of 17.4 mg/kg/day in the 1 year dog study and an uncertainty factor (UF) of 100 to account for inter- and intra-species variability, an RfD of 0.177 mg/kg/day is recommended.

A chronic dietary risk assessment which included all proposed tolerances was conducted on TM-402 using U.S. EPA's Dietary Risk Evaluation System (DRES). The theoretical maximum residue contribution (TMRC) for the U.S. population (48 States) is 0.00125 mg/kg/day and this represents 0.71% of the propoed RfD. The most highly exposed subgroup was children (1- 6 years old) where the TMRC was 0.00382 mg/kg/day, representing only 2.15% of the proposed RfD. For non-nursing infants (>1 year old) the TMRC was 0.00101 mg/kg/day (0.57% of the RfD) and for children 7-12 years old the TMRC is 0.00156 mg/kg/day (0.88% of the RfD). If these calculations consider the average of anticipated residue values instead of assuming ''tolerance level'' residues, the values are reduced to approximately one-third of those listed above. Even under the most conservative assumptions, the estimates of dietary exposure clearly demonstrate adequate safety margins of all segments of the population.

2. *Infants and children*. In assessing the potential for additional sensitivity of infants and children to residues of TM-402, the available developmental toxicity and reproductive toxicity studies and the potential for endocrine modulation by TM-402 were considered. Developmental toxicity studies in two species indicate that TM-402 does not impose additional risks to developing fetuses and is not a teratogen. The 2-generation reproduction study in rats demonstrated that there were no adverse effects on reproductive performance, fertility, fecundity, pup survival, or pup development at non-maternally toxic levels. Maternal and developmental NOAELs and LOAELs were comparable, indicating no increase in susceptibility of developing organisms. No evidence of endocrine effects were noted in any study. It is therefore concluded that TM-402 poses no additional risk for infants and children and no additional uncertainty factor is warranted.

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FEDERAL COMMUNICATIONS COMMISSION

[DA 98–2266; Report No. AUC–99–23–A (Auction No. 23)]

Local Multipoint Distribution Service Spectrum Re-auction of 168 Licenses Scheduled for April 27, 1999; Application Filing Deadline Set for March 29, 1999; Comment Sought on Reserve Prices or Minimum Opening Bids and Other Auction Procedures

AGENCY: Federal Communications Commission.

ACTION: Notice; seeking comment.

SUMMARY: This Public Notice announces the reauction of Local Multipoint Distribution Service (''LMDS'') spectrum, consisting of 168 licenses, set to begin on April 27, 1998, and seeks comment on procedural issues relating to the LMDS reauction.

DATES: Comments are due on or before November 30, 1998. Reply comments are due on or before December 7, 1998.

ADDRESSES: To file formally, parties must submit an original and four copies to the Office of the Secretary, Federal Communications Commission, Federal Communications Commission, 445 Twelfth Street, SW, TW–A325, Washington, DC 20554. In addition, parties must submit one copy to Amy Zoslov, Chief, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, Federal Communications Commission, Room 5202, 2025 M Street NW, Washington, DC 20554. Comments and reply comments will be available for public inspection during regular business hours in the Wireless Telecommunications Bureau Reference Center, Room 5608, 2025 M Street NW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Christina Clearwater, Arthur Lechtman, Tim Salmon, or Kathy Garland, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau, at (202) 418–0660.

SUPPLEMENTARY INFORMATION: This Public Notice was released on November 6, 1998, and is available in its entirety, including the Attachment, for inspection and copying during normal business hours in the Wireless Telecommunications Bureau Reference Center, Room 5608, 2025 M Street NW, Washington, DC, and also may be purchased from the Commission's copy contractor, International Transcription Services, (202) 857–3800, fax (202) 857–3805, 1231 20th Street, NW, Washington, DC 20036. It is also available on the Commission's website at http://www.fcc.gov.

Synopsis of the Public Notice

1. By this Public Notice, the Wireless Telecommunications Bureau (''Bureau'') announces the reauction of 168 Local Multipoint Distribution Service (''LMDS'') licenses set to begin on April 27, 1999. These licenses either received no bids in the original LMDS auction that closed on March 25, 1998 or are defaulted licenses which are available for reauction. Two blocks of spectrum are allocated for LMDS systems:

(1) Block A (1,150 MHz): 27,500–28,350 MHz and 29,100–29,250 MHz and 31,075–31,225 MHz
(2) Block B (150 MHz): 31,000–31,075 MHz and 31,225–31,300 MHz

2. One license will be awarded for each of these spectrum blocks in each of 122 Block A Basic Trading Areas (BTAs) and 46 Block B BTAs designated for LMDS. These licenses are listed in the Attachment to this Public Notice. The BTA licenses designated for the LMDS reauction comprise various portions of the following areas: (1) continental United States and (2) Puerto Rico. Thus, there are a total of 168 LMDS licenses to be reauctioned. Future public notices, will include further details regarding application filing and payment deadlines, a seminar, and other pertinent information. These future public notices will take the place of a bidder package for the LMDS reauction. In this Public Notice, the Bureau seeks comment on procedural issues relating to the LMDS reauction.

Key Dates

Short Form Application (FCC Form 175): March 29, 1999; 5:30 p.m. ET
Upfront Payments (via wire transfer): April 12, 1998; 6:00 p.m. ET
Auction Start: April 27, 1999; TBA

I. Reserve Price or Minimum Opening Bid

3. The Balanced Budget Act of 1997 calls upon the Commission to prescribe methods by which a reasonable reserve price will be required or a minimum opening bid established when FCC licenses are subject to auction (i.e., because the Commission has accepted mutually exclusive applications for those licenses), unless the Commission determines that a reserve price or minimum bid is not in the public interest. Consistent with this mandate, the Commission has directed the Bureau to seek comment on the use of a minimum opening bid and/or reserve price prior to the start of each auction. The Bureau was directed to seek comment on the methodology to be employed in establishing each of these mechanisms. Among other factors the Bureau should consider are the amount of spectrum being auctioned, levels of incumbency, the availability of technology to provide service, the size of the geographic service areas, issues of interference with other spectrum bands, and any other relevant factors that reasonably could have an impact on valuation of the spectrum being auctioned. The Commission concluded that the Bureau should have the discretion to employ either or both of these mechanisms for future auctions.

4. Normally, a reserve price is an absolute minimum price below which an item will not be sold in a given auction. Reserve prices can be either published or unpublished. A minimum opening bid, on the other hand, is the minimum bid price set at the beginning of the auction below which no bids are accepted. It is generally used to accelerate the competitive bidding process. Also, in a minimum opening bid scenario, the auctioneer generally has the discretion to lower the amount later in the auction. It is also possible for the minimum opening bid and the reserve price to be the same amount.

5. In anticipation of this reauction and in light of the Balanced Budget Act, the Bureau proposes to establish minimum opening bids for the LMDS reauction, and retain discretion to lower the minimum opening bids. The Bureau believes a minimum opening bid, which has been utilized in other auctions, is an effective bidding tool. A minimum opening bid, rather than a reserve price, will help to regulate the pace of the auction and provides flexibility.

6. Specifically, for Auction No. 23, the Commission proposes the following license-by-license formulas for calculating minimum opening bids, based on the population (''pops'') of the BTA:

(1) Block A: $0.06 * Pops (rounded up to the next dollar)
(2) Block B: $0.03 * Pops (rounded up to the next dollar)

Comment is sought on this proposal. If commenters believe that the formula proposed above for minimum opening bids will result in substantial numbers of unsold licenses, or is not a reasonable amount, or should instead operate as a reserve price, they should explain why this is so, and comment on the desirability of an alternative approach. Commenters are advised to support their claims with valuation analyses and suggested reserve prices or minimum opening bid levels or formulas. In establishing the formula for minimum opening bids, the Bureau particularly

seeks comment on such factors as, among other things, the amount of spectrum being auctioned, levels of incumbency, the availability of technology to provide service, the size of the geographic service areas, issues of interference with other spectrum bands and any other relevant factors that could reasonably have an impact on valuation of the LMDS spectrum. Alternatively, comment is sought on whether, consistent with the Balanced Budget Act, the public interest would be served by having no minimum opening bid or reserve price.

II. Other Auction Procedures

7. The Balanced Budget Act of 1997 requires the Commission to ''ensure that, in the scheduling of any competitive bidding under this subsection, an adequate period is allowed * * * before issuance of bidding rules, to permit notice and comment on proposed auction procedures * * *'' Consistent with the provisions of the Balanced Budget Act and to ensure that potential bidders have adequate time to familiarize themselves with the specific provisions that will govern the day-to-day conduct of an auction, the Commission directed the Bureau, under its existing delegated authority, to seek comment on a variety of auction-specific procedures prior to the start of each auction. The Bureau therefore seeks comment on the following issues.

a. Auction Sequence and License Groupings

8. Because it is most administratively appropriate, and allows bidders to take advantage of any synergies that exist among licenses, the Commission proposes to award the 168 LMDS licenses in a single, simultaneous multiple-round auction. The Bureau seeks comment on this proposal.

b. Upfront Payments and Initial Maximum Eligibility for Each Bidder

9. The Bureau has delegated authority and discretion to determine an appropriate upfront payment for each license being auctioned, taking into account such factors as the population in each geographic license area, and the value of similar spectrum. With these guidelines in mind, the Bureau proposes for the LMDS reauction the following upfront payments:

(1) Block A: $0.06 * Pops (rounded up to the next dollar)
(2) Block B: $0.03 * Pops (rounded up to the next dollar)

The Bureau seeks comment on this proposal. For the LMDS reauction, the Bureau further proposes that the amount of the upfront payment submitted by a bidder will determine the initial maximum eligibility (as measured in bidding units) for each bidder. Upfront payments will not be attributed to specific licenses, but instead will be translated into bidding units to define a bidder's initial maximum eligibility, which cannot be increased during the auction. Thus, in calculating the upfront payment amount, an applicant must determine the *maximum* number of bidding units it may wish to bid on (or hold high bids on) in any single round, and submit an upfront payment covering that number of bidding units. The Bureau seeks comment on this proposal.

c. Structure of Bidding Rounds, Activity Requirements, and Criteria for Determining Reductions in Eligibility

10. The Bureau proposes to divide the auction into three stages: Stage One, Stage Two and Stage Three. The auction will start in Stage One. The Bureau proposes that the auction will generally advance to the next stage (i.e., from Stage One to Stage Two, and from Stage Two to Stage Three) when the auction activity level, as measured by the percentage of bidding units receiving new high bids, is below ten percent for three consecutive rounds of bidding in each Stage. However, the Bureau further proposes that it retain the discretion to change stages unilaterally by announcement during the auction. In exercising this discretion, the Bureau will consider a variety of measures of bidder activity including, but not limited to, the auction activity level, the percentages of licenses (as measured in bidding units) on which there are new bids, the number of new bids, and the percentage increase in revenue. The Bureau seeks comment on these proposals.

11. In order to ensure that the auction closes within a reasonable period of time, an activity rule requires bidders to bid actively on a percentage of their maximum bidding eligibility during each round of the auction rather than waiting until the end to participate. A bidder that does not satisfy the activity rule will either lose bidding eligibility in the next round or use an activity rule waiver.

12. For the LMDS reauction, the Bureau proposes that, in each round of Stage One of the auction, a bidder desiring to maintain its current eligibility is required to be active on licenses encompassing at least 80 percent of its current bidding eligibility. Failure to maintain the requisite activity level will result in a reduction in the bidder's bidding eligibility in the next round of bidding (unless an activity rule waiver is used). During Stage One, reduced eligibility for the next round will be calculated by multiplying the current round activity by five-fourths (5⁄4). In each round of the second stage of the auction, a bidder desiring to maintain its current eligibility is required to be active on at least 90 percent of its current bidding eligibility. During Stage Two, reduced eligibility for the next round will be calculated by multiplying the current round activity by ten-ninths (10⁄9). In each round of Stage Three, a bidder desiring to maintain its current eligibility is required to be active on 98 percent of its current bidding eligibility. In this final stage, reduced eligibility for the next round will be calculated by multiplying the current round activity by fifty forty-ninths (50⁄49). The Bureau seeks comment on these proposals.

d. Minimum Accepted Bids

13. Once there is a standing high bid on a license, a bid increment will be applied to that license to establish a minimum acceptable bid for the following round. For the LMDS reauction, the Bureau proposes to use a smoothing methodology to calculate bid increments. This methodology will be designed to vary the increment for a given license between a maximum and minimum value based on the bidding activity on that license. A similar methodology was used in previous auctions, including the original LMDS auction and the 220 MHz auction. The Bureau proposes initial values for the maximum of 0.2 or 20% of the license value, and a minimum of 0.1 or 10% of the license value.

14. The Bureau retains the discretion to change these values if circumstances so dictate, such as raising the minimum increment toward the end of the auction to enable bids to reach their final values more quickly. The Bureau will do so by announcement in the Automated Auction System. Under its discretion the Bureau may also implement an absolute dollar floor for the bid increment to further facilitate a timely close of the auction. The Bureau further seeks comment on the advantages and disadvantages of using the discretion to adjust the minimum bid increment without prior notice. As an alternative approach, the Bureau seeks comment on the advantages and disadvantages of adjusting the minimum bid increment gradually over a number of rounds as opposed to single large changes in the minimum bid increment. The Bureau also retains the discretion to use alternate methodologies for the LMDS reauction if circumstances warrant. The

Bureau seeks comment on these proposals.

e. Activity Rule Waivers and Reducing Eligibility

15. Use of an activity rule waiver preserves the bidder's current bidding eligibility despite the bidder's activity in the current round being below the required minimum level. An activity rule waiver applies to an entire round of bidding and not to a particular license. Activity waivers are principally a mechanism for auction participants to avoid the loss of auction eligibility in the event that exigent circumstances prevent them from placing a bid in a particular round.

16. The FCC auction system assumes that bidders with insufficient activity would prefer to use an activity rule waiver (if available) rather than lose bidding eligibility. Therefore, the system will automatically apply a waiver (known as an ''automatic waiver'') at the end of any bidding period where a bidder's activity level is below the minimum required unless: (1) there are no activity rule waivers available; or (2) the bidder overrides the automatic application of a waiver by reducing eligibility, thereby meeting the minimum requirements.

17. A bidder with insufficient activity that wants to reduce its bidding eligibility, rather than use an activity rule waiver, must affirmatively override the automatic waiver mechanism during the bidding period by using the reduce eligibility function in the software. In this case, the bidder's eligibility is permanently reduced to bring the bidder into compliance with the activity rules as described above. Once eligibility has been reduced, a bidder will not be permitted to regain its lost bidding eligibility.

18. A bidder may proactively use an activity rule waiver as a means to keep the auction open without placing a bid. If a bidder submits a proactive waiver (using the proactive waiver function in the bidding software) during a bidding period in which no bids are submitted, the auction will remain open and the bidder's eligibility will be preserved. An automatic waiver invoked in a round in which there are no new valid bids will not keep the auction open.

19. The Bureau proposes that each bidder in the LMDS reauction be provided with five activity rule waivers that may be used in any round during the course of the auction as set forth above. The Bureau seeks comment on this proposal.

f. Information Regarding Bid Withdrawal and Bid Removal

20. For the LMDS reauction, the Bureau proposes the following bid removal and bid withdrawal procedures. Before the close of a bidding period, a bidder has the option of removing any bids placed in that round. By using the remove bid function in the software, a bidder may effectively ''unsubmit'' any bid placed within that round. A bidder removing a bid placed in the same round is not subject to withdrawal payments.

21. Once a round closes, a bidder may no longer remove a bid. However, in the next round, a bidder may withdraw standing high bids from previous rounds using the withdraw bid function. A high bidder that withdraws its standing high bid from a previous round is subject to the bid withdrawal payment provisions. The Bureau seeks comment on these bid removal and bid withdrawal procedures.

22. In the Part 1 Third Report and Order, the Commission recently explained that allowing bid withdrawals facilitates efficient aggregation of licenses and the pursuit of efficient backup strategies as information becomes available during the course of an auction. The Commission noted, however, that, in some instances, bidders may seek to withdraw bids for improper reasons, including to delay the close of the auction for strategic purposes. The Bureau, therefore, has discretion, in managing the auction, to limit the number of withdrawals to prevent strategic delay of the close of the auction or other abuses. The Commission stated that the Bureau should assertively exercise its discretion, consider limiting the number of rounds in which bidders may withdraw bids, and prevent bidders from bidding on a particular market if the Bureau finds that a bidder is abusing the Commission's bid withdrawal procedures.

23. Applying this reasoning, the Bureau proposes to limit each bidder in the LMDS reauction to withdrawals in no more than two rounds during the course of the auction. To permit a bidder to withdraw bids in more than two rounds would likely encourage insincere bidding or the use of withdrawals for anti-competitive strategic purposes. The two rounds in which withdrawals are utilized will be at the bidder's discretion; withdrawals otherwise must be in accordance with the Commission's rules. There is no limit on the number of standing high bids that may be withdrawn in either of the rounds in which withdrawals are utilized. Withdrawals will remain subject to the bid withdrawal payment provisions specified in the Commission's rules. The Bureau seeks comment on this proposal.

g. Stopping Rule

24. For the LMDS reauction, the Bureau proposes to employ a simultaneous stopping approach. The Bureau has discretion ''to establish stopping rules before or during multiple round auctions in order to terminate the auction within a reasonable time.'' A simultaneous stopping rule means that all licenses remain open until the first round in which no new acceptable bids, proactive waivers or withdrawals are received. After the first such round, bidding closes simultaneously on all licenses. Thus, unless circumstances dictate otherwise, bidding would remain open on all licenses until bidding stops on every license.

25. The Bureau seeks comment on a modified version of the simultaneous stopping rule. The modified stopping rule would close the auction for all licenses after the first round in which no bidder submits a proactive waiver, a withdrawal, or a new bid on any license on which it is not the standing high bidder. Thus, absent any other bidding activity, a bidder placing a new bid on a license for which it is the standing high bidder would not keep the auction open under this modified stopping rule. The Bureau further seeks comment on whether this modified stopping rule should be used unilaterally or only in stage three of the auction.

26. The Commission proposes that the Bureau retain the discretion to keep an auction open even if no new acceptable bids or proactive waivers are submitted and no previous high bids are withdrawn. In this event, the effect will be the same as if a bidder had submitted a proactive waiver. The activity rule, therefore, will apply as usual and a bidder with insufficient activity will either lose bidding eligibility or use a remaining activity rule waiver.

27. Finally, the Commission proposes that the Bureau reserve the right to declare that the auction will end after a specified number of additional rounds (''special stopping rule''). If the Bureau invokes this special stopping rule, it will accept bids in the final round(s) only for licenses on which the high bid increased in at least one of the preceding specified number of rounds. The Bureau proposes to exercise this option only in certain circumstances, such as, for example, where the auction is proceeding very slowly, there is minimal overall bidding activity, or it appears likely that the auction will not

close within a reasonable period of time. Before exercising this option, the Bureau is likely to attempt to increase the pace of the auction by, for example, moving the auction into the next stage (where bidders would be required to maintain a higher level of bidding activity), increasing the number of bidding rounds per day, and/or increasing the amount of the minimum bid increments for the limited number of licenses where there is still a high level of bidding activity. The Bureau seeks comment on these proposals.

h. Information Relating to Auction Delay, Suspension or Cancellation

28. For the LMDS reauction, the Commission proposes that, by public notice or by announcement during the auction, the Bureau may delay, suspend or cancel the auction in the event of natural disaster, technical obstacle, evidence of an auction security breach, unlawful bidding activity, administrative or weather necessity, or for any other reason that affects the fair and competitive conduct of competitive bidding. In such cases, the Bureau, in its sole discretion, may elect to: resume the auction starting from the beginning of the current round; resume the auction starting from some previous round; or cancel the auction in its entirety. Network interruption may cause the Bureau to delay or suspend the auction. The Commission emphasizes that exercise of this authority is solely within the discretion of the Bureau, and its use is not intended to be a substitute for situations in which bidders may wish to apply their activity rule waivers. The Bureau seeks comment on this proposal.

Federal Communications Commission.

Daniel B. Phythyon,

Chief, Wireless Telecommunications Bureau.

ATTACHMENT

LMDS REAUCTION—PROPOSED MOB'S AND UPFRONT PAYMENTS: A BLOCK LICENSES

MTA	BTA	Description	License No.	Population (1990 census)	Upfront payment ($.06*Pops)	MOB ($.06*Pops)
M024	B002	Aberdeen, WA	LDB002A	83,057	$4,984	$4,984
M011	B006	Albany-Tifton, GA	LDB006A	324,899	19,494	19,494
M006	B016	Anderson, SC	LDB016A	305,120	18,308	18,308
M029	B017	Anniston, AL	LDB017A	161,897	9,714	9,714
M006	B020	Asheville-Hendersonville, NC	LDB020A	510,055	30,604	30,604
M018	B035	Beckley, WV	LDB035A	167,112	10,027	10,027
M024	B036	Bellingham, WA	LDB036A	127,780	7,667	7,667
M018	B048	Bluefield, WV	LDB048A	184,020	11,042	11,042
M028	B049	Blytheville, AR	LDB049A	79,446	4,767	4,767
M026	B052	Bowling Green-Glasgow, KY	LDB052A	222,748	13,365	13,365
M012	B054	Brainerd, MN	LDB054A	78,465	4,708	4,708
M032	B061	Burlington, IA	LDB061A	137,543	8,253	8,253
M006	B062	Burlington, NC	LDB062A	108,213	6,493	6,493
M001	B063	Burlington, VT	LDB063A	369,128	22,148	22,148
M019	B066	Cape Girardeau-Sikeston, MO	LDB066A	181,795	10,908	10,908
M003	B071	Champaign-Urbana, IL	LDB071A	222,312	13,339	13,339
M021	B082	Clarksburg-Elkins, WV	LDB082A	190,498	11,430	11,430
M032	B086	Clinton, IA-Sterling, IL	LDB086A	147,981	8,879	8,879
M019	B090	Columbia, MO	LDB090A	190,536	11,433	11,433
M011	B092	Columbus, GA	LDB092A	342,333	20,540	20,540
M031	B093	Columbus, IN	LDB093A	139,128	8,348	8,348
M010	B100	Cumberland, MD	LDB100A	156,707	9,403	9,403
M003	B103	Danville, IL	LDB103A	114,241	6,855	6,855
M032	B105	Davenport, IA-Moline, IL	LDB105A	419,650	25,179	25,179
M029	B115	Dothan-Enterprise, AL	LDB115A	210,225	12,614	12,614
M021	B117	Du Bois-Clearfield, PA	LDB117A	124,180	7,451	7,451
M032	B118	Dubuque, IA	LDB118A	176,542	10,593	10,593
M012	B119	Duluth, MN	LDB119A	400,771	24,047	24,047
M028	B120	Dyersburg-Union City, TN	LDB120A	113,943	6,837	6,837
M033	B121	Eagle Pass-Del Rio, TX	LDB121A	100,813	6,049	6,049
M016	B122	East Liverpool-Salem, OH	LDB122A	108,276	6,497	6,497
M012	B123	Eau Claire, WI	LDB123A	180,559	10,834	10,834
M002	B124	El Centro-Calexico, CA	LDB124A	109,303	6,559	6,559
M016	B131	Erie, PA	LDB131A	275,572	16,535	16,535
M004	B134	Eureka, CA	LDB134A	142,578	8,555	8,555
M040	B140	Fayetteville-Springdale-Rogers, AR	LDB140A	222,526	13,352	13,352
M006	B141	Fayetteville-Lumberton, NC	LDB141A	571,328	34,280	34,280
M029	B146	Florence, AL	LDB146A	173,076	10,385	10,385
M006	B147	Florence, SC	LDB147A	239,208	14,353	14,353
M040	B153	Ft. Smith, AR	LDB153A	282,187	16,932	16,932
M010	B156	Fredericksburg, VA	LDB156A	124,654	7,480	7,480
M029	B158	Gadsden, AL	LDB158A	174,034	10,443	10,443
M011	B160	Gainesville, GA	LDB160A***	170,365	10,222	10,222
M003	B161	Galesburg, IL	LDB161A***	75,574	4,535	4,535
M039	B162	Gallup, NM	LDB162A	122,277	7,337	7,337
M001	B164	Glens Falls, NY	LDB164A	118,539	7,113	7,113
M006	B165	Goldsboro-Kinston, NC	LDB165A	217,319	13,040	13,040
M006	B176	Greenville-Washington, NC	LDB176A	218,937	13,137	13,137
M006	B178	Greenwood, SC	LDB178A***	68,435	4,107	4,107

LMDS REAUCTION—PROPOSED MOB'S AND UPFRONT PAYMENTS: A BLOCK LICENSES—Continued

MTA	BTA	Description	License No.	Population (1990 census)	Upfront payment ($.06*Pops)	MOB ($.06*Pops)
M040	B182	Harrison, AR	LDB182A	74,459	4,468	4,468
M040	B193	Hot Springs, AR	LDB193A	117,439	7,047	7,047
M017	B195	Houma-Thibodaux, LA	LDB195A	263,681	15,821	15,821
M008	B201	Hyannis, MA	LDB201A	204,256	12,256	12,256
M021	B203	Indiana, PA	LDB203A	89,994	5,400	5,400
M028	B211	Jackson, TN	LDB211A	255,379	15,323	15,323
M003	B213	Jacksonville, IL	LDB213A***	70,795	4,248	4,248
M006	B214	Jacksonville, NC	LDB214A	149,838	8,991	8,991
M035	B215	Jamestown-Dunkirk, NY-Warren, PA	LDB215A	186,945	11,217	11,217
M020	B216	Janesville-Beloit, WI	LDB216A	214,510	12,871	12,871
M019	B217	Jefferson City, MO	LDB217A	141,404	8,485	8,485
M021	B218	Johnstown, PA	LDB218A	241,247	14,475	14,475
M040	B219	Jonesboro-Paragould, AR	LDB219A	159,439	9,567	9,567
M003	B225	Kankakee, IL	LDB225A	127,042	7,623	7,623
M008	B227	Keene, NH	LDB227A	111,709	6,703	6,703
M031	B233	Kokomo-Logansport, IN	LDB233A	184,899	11,094	11,094
M020	B234	La Crosse, WI-Winona, MN	LDB234A	295,769	17,747	17,747
M031	B235	Lafayette, IN	LDB235A***	247,523	14,852	14,852
M003	B243	La Salle-Peru-Ottawa-Streator, IL	LDB243A	148,331	8,900	8,900
M008	B249	Lebanon-Claremont, NH	LDB249A	167,576	10,055	10,055
M045	B270	McCook, NE	LDB270A**	36,618	2,198	2,198
M011	B271	Macon-Warner Robins, GA	LDB271A	589,208	35,353	35,353
M032	B285	Mason City, IA	LDB285A	118,834	7,131	7,131
M016	B287	Meadville, PA	LDB287A	86,169	5,171	5,171
M004	B291	Merced, CA	LDB291A	192,705	11,563	11,563
M003	B294	Michigan City-La Porte, IN	LDB294A	107,066	6,424	6,424
M044	B295	Middlesboro-Harlan, KY	LDB295A	121,217	7,274	7,274
M031	B309	Muncie, IN	LDB309A	182,386	10,944	10,944
M006	B316	New Bern, NC	LDB316A	154,955	9,298	9,298
M021	B317	New Castle, PA	LDB317A	96,246	5,775	5,775
M001	B319	New London-Norwich, CT	LDB319A	357,482	21,449	21,449
M045	B323	Norfolk, NE	LDB323A	112,526	6,752	6,752
M013	B326	Ocala, FL	LDB326A	194,833	11,690	11,690
M021	B328	Oil City-Franklin, PA	LDB328A	105,882	6,353	6,353
M035	B330	Olean, NY-Bradford, PA	LDB330A	239,343	14,361	14,361
M024	B331	Olympia-Centralia, WA	LDB331A	258,937	15,537	15,537
M006	B335	Orangeburg, SC	LDB335A	114,458	6,868	6,868
M032	B337	Ottumwa, IA	LDB337A	122,988	7,380	7,380
M026	B339	Paducah-Murray-Mayfield, KY	LDB339A	217,082	13,025	13,025
M003	B344	Peoria, IL	LDB344A	455,643	27,339	27,339
M040	B348	Pine Bluff, AR	LDB348A	152,918	9,176	9,176
M008	B351	Pittsfield, MA	LDB351A	139,352	8,362	8,362
M001	B352	Plattsburgh, NY	LDB352A	123,121	7,388	7,388
M019	B355	Poplar Bluff, MO	LDB355A	148,240	8,895	8,895
M019	B367	Quincy, IL-Hannibal, MO	LDB367A	177,213	10,633	10,633
M031	B373	Richmond, IN	LDB373A***	104,942	6,297	6,297
M022	B375	Riverton, WY	LDB375A	46,859	2,812	2,812
M006	B377	Roanoke Rapids, NC	LDB377A	76,314	4,579	4,579
M003	B380	Rockford, IL	LDB380A	412,120	24,728	24,728
M006	B382	Rocky Mount-Wilson, NC	LDB382A	199,296	11,958	11,958
M019	B383	Rolla, MO	LDB383A	98,233	5,894	5,894
M011	B384	Rome, GA	LDB384A***	115,066	6,904	6,904
M040	B387	Russellville, AR	LDB387A	81,863	4,912	4,912
M001	B388	Rutland-Bennington, VT	LDB388A	97,987	5,880	5,880
M005	B390	Saginaw-Bay City, MI	LDB390A	615,364	36,922	36,922
M046	B396	Salina, KS	LDB396A	143,408	8,605	8,605
M034	B414	Sedalia, MO	LDB414A	79,705	4,783	4,783
M016	B416	Sharon, PA	LDB416A	121,003	7,261	7,261
M003	B426	Springfield, IL	LDB426A	254,696	15,282	15,282
M023	B430	Staunton-Waynesboro, VA	LDB430A	100,322	6,020	6,020
M031	B442	Terre Haute, IN	LDB442A	236,968	14,219	14,219
M005	B446	Traverse City, MI	LDB446A	204,600	12,276	12,276
M028	B449	Tupelo-Corinth, MS	LDB449A	291,701	17,503	17,503
M001	B453	Utica-Rome, NY	LDB453A	316,633	18,998	18,998
M037	B454	Valdosta, GA	LDB454A	139,226	8,354	8,354
M014	B456	Victoria, TX	LDB456A	149,963	8,998	8,998
M001	B463	Watertown, NY	LDB463A	296,253	17,776	17,776
M019	B470	West Plains, MO	LDB470A	67,165	4,030	4,030
M018	B474	Williamson, WV-Pikeville, KY	LDB474A	185,682	11,141	11,141
M006	B478	Wilmington, NC	LDB478A	249,711	14,983	14,983

LMDS REAUCTION—PROPOSED MOB'S AND UPFRONT PAYMENTS: A BLOCK LICENSES—Continued

MTA	BTA	Description	License No.	Population (1990 census)	Upfront payment ($.06*Pops)	MOB ($.06*Pops)
M027	B486	Yuma, AZ	LDB486A	106,895	6,414	6,414
M025	B488	San Juan, PR	LDB488A	2,170,246	130,215	130,215
M025	B489	Mayaguez-Aguadilla-Ponce, PR	LDB489A	1,351,600	81,096	81,096
		A Block Totals		26,057,363	1,563,497	1,563,497

*Subject to a pending waiver request filed by New Wave Networks, L.L.C.
**Subject to a pending petition for reconsideration filed by Pinpoint Communications, Inc.
***Baker Creek defaulted on this license.

LMDS REAUCTION—PROPOSED MOB'S AND UPFRONT PAYMENTS: B BLOCK LICENSES

MTA	BTA	Description	License No.	Population (1990)	Upfront payment ($.03*Pops)	MOB ($.03*Pops)
M005	B005	Adrian, MI	LDB005B***	91,476	$2,745	$2,745
M005	B011	Alpena, MI	LDB011B***	63,429	1,903	1,903
M005	B033	Battle Creek, MI	LDB033B***	227,541	6,827	6,827
M030	B038	Bend, OR	LDB038B*	102,745	3,083	3,083
M003	B039	Benton Harbor, MI	LDB039B***	161,378	4,842	4,842
M003	B046	Bloomington, IL	LDB046B***	215,795	6,474	6,474
M019	B066	Cape Girardeau-Sikeston, MO	LDB066B***	181,795	5,454	5,454
M019	B067	Carbondale-Marion, IL	LDB067B***	209,497	6,285	6,285
M032	B070	Cedar Rapids, IA	LDB070B***	260,686	7,821	7,821
M032	B086	Clinton, IA-Sterling, IL	LDB086B***	147,981	4,440	4,440
M019	B090	Columbia, MO	LDB090B***	190,536	5,717	5,717
M030	B097	Coos Bay-North Bend, OR	LDB097B	79,600	2,388	2,388
M003	B109	Decatur-Effingham, IL	LDB109B***	247,608	7,429	7,429
M004	B134	Eureka, CA	LDB134B	142,578	4,278	4,278
M012	B142	Fergus Falls, MN	LDB142B***	120,167	3,606	3,606
M027	B144	Flagstaff, AZ	LDB144B*	96,591	2,898	2,898
M005	B145	Flint, MI	LDB145B***	500,229	15,007	15,007
M039	B162	Gallup, NM	LDB162B	122,277	3,669	3,669
M046	B163	Garden City, KS	LDB163B	65,059	1,952	1,952
M005	B169	Grand Rapids, MI	LDB169B***	916,060	27,482	27,482
M045	B185	Hastings, NE	LDB185B**	72,833	2,185	2,185
M005	B209	Jackson, MI	LDB209B***	193,187	5,796	5,796
M019	B217	Jefferson City, MO	LDB217B***	141,404	4,243	4,243
M005	B223	Kalamazoo, MI	LDB223B***	352,384	10,572	10,572
M005	B241	Lansing, MI	LDB241B***	489,698	14,691	14,691
M039	B244	Las Cruces, NM	LDB244B	197,166	5,915	5,915
M047	B254	Lihue, HI	LDB254B*	51,177	1,536	1,536
M045	B270	McCook, NE	LDB270B**	36,618	1,099	1,099
M012	B277	Mankato-Fairmont, MN	LDB277B***	245,144	7,355	7,355
M004	B303	Modesto, CA	LDB303B	418,978	12,570	12,570
M005	B307	Mt. Pleasant, MI	LDB307B***	118,558	3,557	3,557
M019	B308	Mt. Vernon-Centralia, IL	LDB308B***	119,286	3,579	3,579
M005	B310	Muskegon,MI	LDB310B***	206,974	6,210	6,210
M003	B344	Peoria, IL	LDB344B***	455,643	13,670	13,670
M019	B355	Poplar Bluff, MO	LDB355B***	148,240	4,448	4,448
M024	B356	Port Angeles, WA	LDB356B	76,610	2,299	2,299
M008	B363	Presque Isle, ME	LDB363B	86,936	2,609	2,609
M004	B371	Redding, CA	LDB371B*	253,255	7,598	7,598
M004	B372	Reno, NV	LDB372B*	439,279	13,179	13,179
M012	B378	Rochester-Austin-Albert Lea, MN	LDB378B***	233,167	6,996	6,996
M019	B383	Rolla, MO	LDB383B***	98,233	2,947	2,947
M036	B392	St. George, UT	LDB392B*	83,263	2,498	2,498
M034	B414	Sedalia, MO	LDB414B***	79,705	2,392	2,392
M003	B426	Springfield, IL	LDB426B***	254,696	7,641	7,641
M032	B462	Waterloo-Cedar Falls, IA	LDB462B***	261,009	7,831	7,831
M019	B470	West Plains, MO	LDB470B***	67,165	2,015	2,015
		B Block Totals		9,323,636	279,731	279,731
		Totals		35,380,999	$1,843,228	$1,843,22

*Subject to a pending waiver request filed by New Wave Networks, LL.C.
**Subject to a pending petition for reconsideration filed by Pinpoint Communications, Inc.
***Baker Creek defaulted on this license.

[FR Doc. 98–30979 Filed 11–19–98; 8:45 am]
BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[DA 98–1897]

Wireless Telecommunications Bureau Provides Guidance on Grace Period and Installment Payment Rules

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this Public Notice, the Wireless Telecommunications Bureau (Bureau) provides guidance to licensees participating in installment payment programs regarding the revised rules governing grace periods and installment payments. This Notice is intended to assist licensees in the transition from the prior rules for late payments to the new rules and policies that are now effective.

FOR FURTHER INFORMATION CONTACT: Rachel Kazan or Rita Cookmeyer, Auctions and Industry Analysis Division, Wireless Telecommunications Bureau at (202) 418–0660.

SUPPLEMENTARY INFORMATION: This public notice was released on September 18, 1998 and is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY–C404, 445 Twelfth Street, SW, Washington, DC and also may be purchased from the Commission's copy contractor, International Transcription Services, (202) 857–3800, fax (202) 857–3805, 1231 20th Street, NW, Washington, DC 20036.

Synopsis of the Public Notice

Background

A. Prior Rules for Late Payment

Installment payment rules, including late payment and grace period rules, are generally codified at 47 CFR 1.2110. Before this rule was amended, it permitted a licensee to make a payment up to 90 days late without being assessed a late payment charge and without being considered in default. If a licensee required additional time to pay beyond the 90 day period, it could submit a formal request for a ''grace period'' of up to 6 months. The licensee would not be considered in default during a grace period, nor would the licensee be declared in default during the pendency of such request.

B. New Rules Now Apply

The Commission recently amended 47 CFR 1.2110 to provide that licensees that do not make an installment payment on or before a due date are automatically granted a 90 day grace period (''non-delinquency period'') and assessed a late fee equal to 5 percent of the missed installment payment (''late fee''). If remittance of the missed installment payment and the 5 percent late fee is not made on or before expiration of the non-delinquency period, a second 90 day period (''grace period'') is automatically granted and an additional late fee equal to 10 percent of the missed installment payment is assessed. Licensees are not required to make an application to the Commission to receive the non-delinquency period or the grace period. Furthermore, licensees are not required to remit the 5 percent late fee prior to the expiration of the non-delinquency period to be eligible for the grace period. Late fees accrue on the first business day after a missed installment payment and upon the expiration of the non-delinquency period.

Specifically, under the revised rule, a licensee must pay the missed installment payment, the 5 percent late fee, the 10 percent late fee (if applicable) and any lender advances the licensee may be obligated to pay (including but not limited to Uniform Commercial Code filing fees and attorney fees for debt collection). This payment must be made in full, in one payment, before the expiration of the non-delinquency period or grace period. Payments made during a non-delinquency period or a grace period shall be applied in the following order of priorities: (i) Lender advances, (ii) late fees, (iii) interest payable, and (iv) principal owed.

Any licensee that becomes more than one-hundred eighty (180) days delinquent on an installment payment shall be in default, and the license shall automatically cancel without further action by the Commission. In that event, the debt shall be transferred to the Department of Treasury for collection subject to the Debt Collection Improvement Act of 1996.

Payment due dates for missed installment payments and accompanying late fee(s) are independent of the regular installment payment schedules. Licensees should be aware that the late payment provisions are calculated on a 90 calendar day basis, while installment payments are based on a quarterly payment schedule. Quarterly payments may cover up to 92 calendar days, depending upon the month in which the payment is due. In many instances, missed installment payments and accompanying late fee(s) may be due before the next quarterly installment payment. Payments of missed installment payments and accompanying late fee(s) must be made simultaneously and in a timely manner. Partial payments will not be sufficient to avoid default.

C. Pending Grace Period Requests

The amendments to 47 CFR 1.2110 became effective March 16, 1998, 60 days after publication of those amendments in the **Federal Register**. Installment payments which were due prior to March 16, 1998, will continue to be processed under the former § 1.2110 of the Commission's rules. Any properly filed requests for a grace period pending under the former Section 1.2110 will be addressed. Furthermore, the late payment and automatic cancellation provisions of amended § 1.2110 will not apply to licenses with properly filed grace period requests until such time as the Bureau addresses these grace period requests. After the resolution of grace period requests, licensees will be subject to the revised grace period rules for future installment payment obligations.

D. Example

The following illustrates how the late payment procedures will now operate. ABC Company has a $100,000 installment payment due on March 31. If ABC Company is able to make its installment payment on March 31, then it must remit $100,000 to the Commission. If ABC Company makes its installment payment anytime from April 1 until June 29 (the end of the 90 day non-delinquency period), then ABC Company must remit $105,000 to the Commission to be considered current on its March 31 installment payment. If ABC Company does not make its March 31 installment payment by June 29, then it must remit $115,000 on or before September 27, which is 180 calendar days after March 1. If ABC Company does not remit the required $115,000 by September 27 (the end of the 90 day grace period), then it will be considered in default and its license will automatically cancel on September 28 without further action by the Commission.

ABC Company's June 30 installment payment of $100,000 remains due on June 30 regardless of the payment status of the March 31 installment payment. The late payment terms apply to June 30 installment payment independently of the March installment payment. Thus, if ABC Company does not make its March 31 installment payment until June 30,

the total amount due to the Commission on June 30 is $215,000, which consists of the March installment payment, the March 5% non-delinquency late fee, the March 10% grace period late fee and the June 30 payment.

Federal Communications Commission.

Dan Phythyon,

Chief, Wireless Telecommunications Bureau.

[FR Doc. 98–31033 Filed 11–19–98; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:15 a.m. on Tuesday, November 17, 1998, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's corporate, resolution, and supervisory activities.

In calling the meeting, the Board determined, on motion of Vice Chairman Andrew C. Hove, Jr., seconded by Director Ellen S. Seidman (Director, Office of Thrift Supervision), concurred in by Director Julie L. Williams (Acting Comptroller of the Currency) and Chairman Donna Tanoue, that Corporation business required its consideration of the matter on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matter in a meeting open to public observation; and that the matter could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c))6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), (c)(9)(B), and (c)(10)).

The meeting was held in the Board Room of the FDIC Building located at 550–17th Street, N.W., Washington, D.C.

Dated: November 18, 1998.

Federal Deposit Insurance Corporation.

James D. LaPierre,

Deputy Executive Secretary.

[FR Doc. 98–31274 Filed 11–18–98; 3:47 pm]

BILLING CODE 6714–01–M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as ocean freight forwarders pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718 and 46 CFR 510).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, DC 20573.

D.C. James & Co., Inc.
2507 Forest Haven Blvd.
Edison, NJ 08817
Officers:
Damian C. James-Mbadugha, President
Tobenna James, Director

Barsan International, Inc.
401 Broadway, Suite 2210
New York, NY 10013
Officers:
Meltem Marasli, President
Norman Isacoff, Vice President

World Shipping America Inc.
333 Sylvan Avenue, Suite 209
Englewood Cliffs, NJ 07632
Officers:
Kun Zhang, President
Joseph Chin Aleong, Vice President
Dated: November 17, 1998.

Joseph C. Polking,

Secretary.

[FR Doc. 98–31057 Filed 11–19–98; 8:45 am]

BILLING CODE 6730–01–M

FEDERAL MARITIME COMMISSION

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Federal Maritime Commission.

TIME AND DATE: 9:00 A.M.—November 24, 1998.

PLACE: 800 North Capitol Street, N.W., First Floor Hearing Room, Washington, D.C.

STATUS: A portion of the meeting will be open to the public and the remainder of the meeting will be closed.

MATTER(S) TO BE CONSIDERED

The Open Portion of the Meeting:

1. Proposed Rules (46 CFR) Implementing the Ocean Shipping Reform Act.

a. Rules of Practice and Procedure including special docket provisions (Part 502).

b. Rules relating to actions to address restrictive maritime practices of foreign governments (Parts 585, 587, 588).

c. Controlled carrier provisions. The Portion closed to the Public:

1. Docket No. 96–06—*River Parishes Company, Inc.* v. *Ormet Primary Aluminum Corp.*—Consideration of the Record.

CONTACT PERSON FOR MORE INFORMATION: Joseph C. Polking, Secretary, (202) 523–5725.

Joseph C. Polking,

Secretary.

[FR Doc. 98–31150 Filed 11–17–98; 4:45 pm]

BILLING CODE 6730–01–M

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than December 4, 1998.

A. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President) 90 Hennepin Avenue, P.O. Box 291, Minneapolis, Minnesota 55480–0291:

1. Campbell Family Limited Partnership II, Dunseith, North Dakota; to acquire voting shares of Security Bancshares, Inc., Dunseith, North Dakota, and thereby indirectly acquire voting shares of Security State Bank, Dunseith, North Dakota.

B. Federal Reserve Bank of Kansas City (D. Michael Manies, Assistant Vice President) 925 Grand Avenue, Kansas City, Missouri 64198–0001:

1. Grady Grissom, Syracuse, Kansas; to acquire voting shares of Valley Bancorp, Inc., Syracuse, Kansas, and thereby indirectly acquire voting shares of The Valley State Bank, Syracuse, Kansas.

Board of Governors of the Federal Reserve System, November 16, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–31017 Filed 11–19–98; 8:45 am]

BILLING CODE 6210–01–F

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act. Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 14, 1998.

A. Federal Reserve Bank of Atlanta (Lois Berthaume, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303-2713:

1. Regions Financial Corporation, Birmingham, Alabama; to merge with Arkansas Banking Company, Jonesboro, Arkansas, and thereby indirectly acquire The Arkansas Bank, Jonesboro, Arkansas; The Arkansas Bank, Walnut Ridge, Arkansas; The Planters Bank, Osceola, Arkansas; and The Arkansas Bank, N.A., Batesville, Arkansas.

B. Federal Reserve Bank of Chicago (Philip Jackson, Applications Officer) 230 South LaSalle Street, Chicago, Illinois 60690-1413:

1. New Century Bancorp, Southfield, Michigan; to become a bank holding company by acquiring 100 percent of the voting shares of New Century Bank, Southfield, Michigan (in organization).

2. Tower Financial Corporation, Fort Wayne, Indiana; to become a bank holding company by acquiring 100 percent of the voting shares of Tower Bank & Trust Company, Fort Wayne, Indiana (in organization).

C. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. Union Planters Corporation, Memphis, Tennessee, and its wholly owned subsidiary, Union Planters Holding Corporation, Memphis, Tennessee; to acquire 100 percent of the voting shares of Southeast Bancorp, Inc., Corbin, Kentucky, and thereby indirectly acquire The First National Bank and Trust Company of Corbin, Corbin, Kentucky, and First Bank of East Tennessee, N.A., LaFollette, Tennessee.

D. Federal Reserve Bank of San Francisco (Maria Villanueva, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. Heritage Financial Corporation, Olympia, Washington; to merge with Harbor Bancorp, Inc., Aberdeen, Washington, and thereby indirectly acquire Bank of Grays Harbor, Aberdeen, Washington.

2. Heritage Financial Corporation, Olympia, Washington; to merge with Washington Independent Bancshares, Inc., Toppenish, Washington, and thereby indirectly acquire Central Valley Bank, National Association, Toppenish, Washington.

Board of Governors of the Federal Reserve System, November 16, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–31019 Filed 11–9–8; 8:45 am]

BILLING CODE 6210–1–F

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities; Correction

This notice corrects a notice (FR Doc. 98-30096) published on page 63055 of the issue for Tuesday, November 10, 1998.

Under the Federal Reserve Bank of Minneapolis heading, the entry for U.S. Bancorp, Minneapolis, Minnesota, is revised to read as follows:

A. Federal Reserve Bank of Minneapolis (JoAnne F. Lewellen, Assistant Vice President) 90 Hennepin Avenue, P.O. Box 291, Minneapolis, Minnesota 55480-0291:

1. U.S. Bancorp, Minneapolis, Minnesota; to acquire Libra Investments, Inc., Los Angeles, California, through this acquisition, U.S. Bancorp will acquire an equity interest in Libra Investors, LLC, LFM, LLC, Libra Investors II, LLC, and LFC, LLC, all of Los Angeles, California, and thereby engage in underwriting and dealing in, to a limited extent, all types of debt and equity securities other than open-end investment companies. *J.P. Morgan & Co., Incorporated*, 75 Fed. Res. Bull. 192 (1989). Engaging in financial advisory activities pursuant to § 225.28(b)(6) of Regulation Y; providing agency transactional services for customer investments, pursuant to § 225.28(b)(7) of Regulation Y; acting directly or indirectly through subsidiaries or affiliates, as general partner for a series of limited partnerships and limited liability companies now existing or to be established in the future, that are excluded from the definition of ''investment company'' under the Investment Company Act of 1940 and are exempt from registration and the prospectus requirements of the Securities Act of 1933, which may invest in securities or other assets eligible for investment by U.S. Bancorp and may make, service and invest in discounted bank loans and other debt securities (other than discounted debt securities collateralized by shares of banks and bank holding companies), including secured and unsecured debt in the form of bank loans, privately placed and publicly-traded debt instruments, bonds, notes, debentures and discounted receivables. *Dresdner Bank AG*, 84 Fed. Res. Bull. 361 (1998); Letter to Swiss Bank Corporation from the Federal Reserve Bank of New York (March 28, 1995); *Meridian Bancorp, Inc.*, 80 Fed. Res. Bull. 736 (1991).

Comments on this application must be received by November 24, 1998.

Board of Governors of the Federal Reserve System, November 16, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–31018 Filed 11–9–8; 8:45 am]

BILLING CODE 6210–1–

FEDERAL RESERVE SYSTEM

Notice of Proposals to Engage in Permissible Nonbanking Activities or to Acquire Companies that are Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or

other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than December 4, 1998.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. German American Bancorp, Jasper, Indiana; to acquire 1st Bancorp, Vincennes, Indiana, and thereby indirectly acquire First Federal Bank, a Federal Savings Bank, Vincennes, Indiana, and thereby engage in the operation of a thrift, pursuant to § 225.28(b)(4)(ii) of Regulation Y; and Financial Services of Southern indiana Corp;, Vincennes, Indiana, and thereby engage in community development activities through making equity and debt investments in corporations or projects designed to promote community welfare, pursuant to § 225.28(b)(12)(i) of Regulation Y.

B. Federal Reserve Bank of San Francisco (Maria Villanueva, Manager of Analytical Support, Consumer Regulation Group) 101 Market Street, San Francisco, California 94105-1579:

1. Wells Fargo & Company, San Francisco, California; Norwest Mortgage, Inc., Des Moines, Iowa; and Norwest Ventures, LLC, Des Moines, Iowa; to engage *de novo* in a joint venture through their subsidiary, Service Mortgage Group, LLC, Louisville, Kentucky, in residential mortgage lending, pursuant to § 225.28(b)(1) of Regulation Y.

2. Wells Fargo & Company, San Francisco, California; Norwest Mortgage, Inc., Des Moines, Iowa; and Norwest Ventures, LLC, Des Moines, Iowa; to engage *de novo* in a joint venture through their subsidiary, Academy Financial Services, LLC, Alpharetta, Georgia, in residential mortgage lending, pursuant to § 225.28(b)(1) of Regulation Y.

Board of Governors of the Federal Reserve System, November 16, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–31020 Filed 11–9–8; 8:45 am]

BILLING CODE 6210–1–F

FEDERAL RESERVE SYSTEM

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 10:00 a.m., Wednesday, November 25, 1998.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, N.W., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any matters carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at http://www.federalreserve.gov for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: November 18, 1998.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 98–31188 Filed 11–18–98; 11:03 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for HIV, STD and TB Prevention (NCHSTP), of the Centers for Disease Control and Prevention (CDC) Announces the Following Meeting

Name: HIV Prevention for Gay Men of Color Consultation.

Times and Dates: 9 a.m.–5 p.m., December 2, 1998. 9 a.m.–5 p.m., December 3, 1998.

Place: The Sheraton Colony Square Hotel Midtown Atlanta, 188 14th Street, N. E., Atlanta, Georgia 30361.

Status: Open to the public for observation and comment, limited only by space available. The meeting room accommodates approximately 65 people.

Purpose: The purpose of this meeting is to provide a forum for consultation and discussion among Gay Men of Color (African Americans, Latinos, Asian and Pacific Islanders, and Native Americans). Participants will represent non-governmental organizations and the Division of HIV/AIDS Prevention (DHAP), NCHSTP. The discussion will address challenges faced by organizations in developing/implementing HIV/AIDS prevention interventions for gay men of color; and examine issues related to organizational capacity building for organizations serving gay men of color.

Matters To Be Discussed: HIV/AIDS surveillance activities related to gay men of color; and analyses and trend data for gay men of color, e.g., geographical trends, data regarding men having sex with other men vs. other populations at risk, etc.

Agenda items are subject to change as priorities dictate.

Contacts for More Information: Janet Cleveland or Yulonda Williams, Division of HIV/AIDS Prevention—Intervention Research and Support, National Center for HIV, STD and TB Prevention, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, m/s E–35, Atlanta, Georgia 30333, telephone 404/639–5200.

The Director, Management Analysis and Services office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: November 16, 1998.

John C. Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–31021 Filed 11–19–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97C–0171]

Closure Medical Corp.; Withdrawal of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal, without prejudice to future filing, of a color additive petition (CAP 7C0250) proposing that the color additive regulations be amended to

provide for the safe use of D&C Violet No. 2 to color 2-octyl cyanoacrylate topical tissue adhesives.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3089.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 1, 1997 (62 FR 23781), FDA announced that a color additive petition (CAP 7C0250) had been filed by Closure Medical Corp., 5265 Capital Blvd., Raleigh, NC 27616 (currently 5250 Greens Dairy Rd., Raleigh, NC 27616). The petition proposed to amend the color additive regulations in § 74.3602 D&C Violet No. 2 (21 CFR 74.3602) to provide for the safe use of D&C Violet No. 2 to color 2-octyl cyanoacrylate topical tissue adhesives.

With the passage of the Medical Device Amendments of 1976 (Pub. L. 94–295), Congress mandated the listing of color additives for use in medical devices when the color additive in the device comes into direct contact with the body for a significant period of time (21 U.S.C. 379e(a)). Since the filing of this petition, the agency has determined that the proposed use of the subject topical tissue adhesives, and therefore, any color additive used in these adhesives, would not contact the body for a significant period of time (Ref. 1). Consequently, the petitioned use of D&C Violet No. 2 is exempt from the statutory listing requirement. Therefore, Closure Medical Corp. has now withdrawn the petition without prejudice to a future filing (21 CFR 71.6(c)(2)) (Ref. 2).

The agency received two comments on the safety of D&C Violet No. 2 in response to the notice of filing for this petition. Arts, Crafts & Theater Safety, Inc. (ACTS) commented that D&C Violet No. 2 could possibly be a carcinogen, based on studies of other anthraquinone dyes and structurally related compounds that concluded those substances were reasonably anticipated to be human carcinogens. They stated that the petition should be denied unless D&C Violet No. 2 is studied for cancer effects and found to show no evidence of carcinogenicity. In response to ACTS'' comment, Flamm Associates commented that in addition to a consideration of the general chemical class of a substance, other structural features need to be evaluated in determining the carcinogenic potential of a substance. They further stated that D&C Violet No. 2 has been tested for carcinogenicity and found to be noncarcinogenic.

The agency concludes that, although the subject petition is being withdrawn, the safety of the currently approved uses of D&C Violet No. 2 (21 CFR 74.1602, 74.2602 and 74.3602) is supported by an extensive body of toxicity testing data and that the comments provide no basis for a safety concern.

References

The following references have been placed on display in the Dockets Management Branch (HFA–305), 5630 Fishers Lane, Rockville, MD 20852 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum from Office of Device Evaluation, Program Operations Staff (Center for Devices and Radiological Health, FDA), to Division of Petition Control (Center for Food Safety and Applied Nutrition, FDA), concerning ''CAP 7C0250'', dated October 23, 1998.

2. Letter from Hyman, Phelps & McNamara, P.C., to Office of Premarket Approval (FDA), dated August 25, 1998.

Dated: November 3, 1998.

Laura M. Tarantino,

Acting Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–31030 Filed 11–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0378]

Agency Information Collection Activities; Announcement of OMB Approval; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Color Additive Certification Requests and Recordkeeping'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: Margaret R. Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 1, 1998 (63 FR 46461), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (44 U.S.C. 3507). An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0216. The approval expires on October 31, 2001.

Dated: November 12, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–31031 Filed 11–19–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the teleconference meeting of the Advisory Committee for Women's Services of the Substance Abuse and Mental Health Services Administration (SAMHSA) in December 1998.

The meeting of the Advisory Committee for Women's Services will include a discussion of the role and responsibilities of the Advisory Committee in providing advice to SAMHSA, and policy and program issues relating to women's substance abuse and mental health service needs at SAMHSA, including the Fiscal Year 1999 budget and SAMHSA's FY 1999 Knowledge Development and Application Grants.

Public comments are welcome. Please communicate with the individual listed as Contact below to make arrangements to comment or to request special accommodations for persons with disabilities.

A summary of the meeting and/or a roster of committee members may be obtained from: Pamela M. Perry, Executive Secretary, Advisory Committee for Women's Services, Women, Children and Families Team, SAMHSA, Parklawn Building, Room 13–99, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–7625, e-mail: pperry@samhsa.gov.

Substantive information may be obtained from the contact whose name and telephone number is listed below.

Committee Name: Advisory Committee for Women's Services.

Meeting Date(s): December 18, 1998.

Place: Room 12–94, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Open: December 18, 1998; 2:00 p.m. to 4:30 p.m.

Contact: Pamela M. Perry, Room 13–99, Parklawn Building, Telephone (301) 443–7625.

Dated: November 16, 1998.

Jeri Lipov,

Committee Management Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 98–31032 Filed 11–19–98; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4341–N–36]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, room 7256, Department of Housing and Urban Development, 451 Seventh Street SW, Washington, DC 20410; telephone (202) 708–1226; TTY number for the hearing- and speech-impaired (202) 708–2565 (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with 24 CFR part 581 and section 501 of the Stewart B. McKinney Homeless Assistance Act (42 U.S.C. 11411), as amended, HUD is publishing this Notice to identify Federal buildings and other real property that HUD has reviewed for suitability for use to assist the homeless. The properties were reviewed using information provided to HUD by Federal landholding agencies regarding unutilized and underutilized buildings and real property controlled by such agencies or by GSA regarding its inventory of excess or surplus Federal property. This Notice is also published in order to comply with the December 12, 1988 Court Order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.).

Properties reviewed are listed in this Notice according to the following categories: Suitable/available, suitable/unavailable, suitable/to be excess, and unsuitable. The properties listed in the three suitable categories have been reviewed by the landholding agencies, and each agency has transmitted to HUD: (1) Its intention to make the property available for use to assist the homeless, (2) its intention to declare the property excess to the agency's needs, or (3) a statement of the reasons that the property cannot be declared excess or made available for use as facilities to assist the homeless.

Properties listed as suitable/available will be available exclusively for homeless use for a period of 60 days from the date of this Notice. Homeless assistance providers interested in any such property should send a written expression of interest to HHS, addressed to Brian Rooney, Division of Property Management, Program Support Center, HHS, room 5B–41, 5600 Fishers Lane, Rockville, MD 20857; (301) 443–2265. (This is not a toll-free number.) HHS will mail to the interested provider an application packet, which will include instructions for completing the application. In order to maximize the opportunity to utilize a suitable property, providers should submit their written expressions of interest as soon as possible. For complete details concerning the processing of applications, the reader is encouraged to refer to the interim rule governing this program, 24 CFR part 581.

For properties listed as suitable/to be excess, that property may, if subsequently accepted as excess by GSA, be made available for use by the homeless in accordance with applicable law, subject to screening for other Federal use. At the appropriate time, HUD will publish the property in a Notice showing it as either suitable/available or suitable/unavailable.

For properties listed as suitable/unavailable, the landholding agency has decided that the property cannot be declared excess or made available for use to assist the homeless, and the property will not be available.

Properties listed as unsuitable will not be made available for any other purpose for 20 days from the date of this Notice. Homeless assistance providers interested in a review by HUD of the determination of unsuitability should call the toll free information line at 1–800–927–7588 for detailed instructions or write a letter to Mark Johnston at the address listed at the beginning of this Notice. Included in the request for review should be the property address (including zip code), the date of publication in the **Federal Register**, the landholding agency, and the property number.

For more information regarding particular properties identified in this Notice (*i.e.,* acreage, floor plan, existing sanitary facilities, exact street address), providers should contact the appropriate landholding agencies at the following addresses: *ARMY:* Mr. Jeff Holste, U.S. Army Corps of Engineers, Installation Support Center, Facilities Management, 7701 Telegraph Road, Alexandria, VA 22315–3862; (703) 428–6318; *ENERGY:* Ms. Marsha Penhaker, Department of Energy, Facilities Planning and Acquisition Branch, FM–20, Room 6H–058, Washington, DC 20585; (202) 586–0426; *NAVY:* Mr. Charles C. Cocks, Department of the Navy, Director, Real Estate Policy Division, Naval Facilities Engineering Command, Code 241A, 200 Stovall Street, Alexandria, VA 22332–2300; (703) 325–7342; (These are not toll-free numbers).

Dated: November 12, 1998.

Fred Karnas, Jr.,

Deputy Assistant Secretary for Economic Development.

Title V, Federal Surplus Property Program Federal Register Report for 11/20/98

Suitable/Available Properties

Buildings (by State)

Alabama

Bldg. 401
Anniston Army Depot
Anniston AL 36201–
Landholding Agency: Army
Property Number: 219840124
Status: Unutilized
Comment: 5161 sq. ft., needs rehab, most recent use—heating plant, off-site use only

Bldg. 172
Anniston Army Depot
Anniston AL 36201–
Landholding Agency: Army
Property Number: 219840125
Status: Unutilized
Comment: 5895 sq. ft., needs rehab, most recent use—demolition shop, off-site use only

Bldg. 88
Anniston Army Depot
Anniston AL 36201–
Landholding Agency: Army
Property Number: 219840126
Status: Unutilized
Comment: 5360 sq. ft., needs rehab, most recent use—renovation shop, off-site use only

Arizona

13 Bldgs.
Fort Huachuca
Sierra Vista Co: Cochise AZ 85635–
Location: 15545, 22412, 22531, 30120, 30123, 70916, 71915, 71917, 71918, 71920, 72914, 72915, 72917
Landholding Agency: Army
Property Number: 219840127
Status: Excess

Comment: various sq. ft., presence of asbestos/lead paint, most recent use—storage/office/training, off-site use only

18 Bldgs.
Fort Huachuca
Sierra Vista Co: Cochise AZ 85635–
Location: 20015–20029, 22404, 30118, 57470
Landholding Agency: Army
Property Number: 219840128
Status: Excess
Comment: various sq. ft., presence of asbestos/lead paint, most recent use—guest housing/office/storage, off-site use only

8 Bldgs.
Fort Huachuca
Sierra Vista Co: Cochise AZ 85635–
Location: 46708, 46709, 46710, 44101, 44102, 44124, 44125, 44201,
Landholding Agency: Army
Property Number: 219840129
Status: Excess
Comment: various sq. ft. & bdrm units, presence of asbestos/lead paint, most recent use—family housing, off-site use only

Georgia

Bldg. T–288
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219840130
Status: Excess
Comment: 2500 sq. ft., poor condition, most recent use—MP station, off-site use only

Bldg. T–291
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219840131
Status: Excess
Comment: 5220 sq. ft., poor condition, most recent use—MP station, off-site use only

Bldg. T–292
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219840132
Status: Excess
Comment: 5220 sq. ft., poor condition, most recent use—MP station, off-site use only

Bldg. 294
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219840133
Status: Excess
Comment: 5220 sq. ft., poor condition, most recent use—admin., off-site use only

Bldg. T–922
Fort Stewart
Hinesville Co: Liberty GA 31314–
Landholding Agency: Army
Property Number: 219840134
Status: Excess
Comment: 2436 sq. ft., poor condition, most recent use—admin., off-site use only

Iowa

Bldg. 46
Des Moines Reserve Complex
Des Moines Co: Polk IA 50315–5899
Landholding Agency: Army
Property Number: 219840135
Status: Unutilized
Comment: 20,944 sq. ft., presence of asbestos/lead paint, most recent use—officer quarters/admin., historical/National Register

Bldg. 49
Des Moines Reserve Complex
Des Moines Co: Polk IA 50315–5899
Landholding Agency: Army
Property Number: 219840136
Status: Underutilized
Comment: 2100 sq. ft., most recent use—chapel, historical/National Register

Maryland

Bldg. 39
Aberdeen Proving Ground Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 219840137
Status: Unutilized
Comment: 2791 sq. ft., presence of asbestos/lead paint, most recent use—housing, off-site use only

Bldg. 0459E
Aberdeen Proving Ground Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 219840138
Status: Unutilized
Comment: 320 sq. ft., poor condition, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 1102B
Aberdeen Proving Ground Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 219840139
Status: Unutilized
Comment: 1600 sq. ft., presence of asbestos/lead paint, most recent use—admin., off-site use only

Bldg. E1455
Aberdeen Proving Ground Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 219840140
Status: Unutilized
Comment: 36 sq. ft., poor condition, presence of asbestos/lead paint, most recent use—guard shack, off-site use only

Bldg. E2328
Aberdeen Proving Ground Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 219840141
Status: Unutilized
Comment: 4171 sq. ft., concrete, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. E2380
Aberdeen Proving Ground Co: Harford MD 21005–5001
Landholding Agency: Army
Property Number: 219840142
Status: Unutilized
Comment: 4171 sq. ft., concrete, presence of asbestos/lead paint, most recent use—storage, off-site use only

New York

Bldg. T–35
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840143
Status: Unutilized
Comment: 1296 sq. ft., most recent use—admin., off-site use only

Bldg. S–149
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840144
Status: Unutilized
Comment: 2488 sq. ft., most recent use—admin., off-site use only

Bldg. T–250
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840145
Status: Unutilized
Comment: 2360 sq. ft., most recent use—storage, off-site use only

Bldg. T–254
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840146
Status: Unutilized
Comment: 4720 sq. ft., most recent use—barracks, off-site use only

Bldg. T–260
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840147
Status: Unutilized
Comment: 2371 sq. ft., most recent use—HQ bldg., off-site use only

Bldg. T–261
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840148
Status: Unutilized
Comment: 1144 sq. ft., most recent use—HQ bldg., off-site use only

Bldg. T–262
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840149
Status: Unutilized
Comment: 1144 sq. ft., most recent use—HQ bldg., off-site use only

Bldg. T–340
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840150
Status: Unutilized
Comment: 2360 sq. ft., most recent use—storage, off-site use only

Bldg. T–392
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840151
Status: Unutilized
Comment: 2740 sq. ft., most recent use—storage, off-site use only

Bldg. T–413
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840152
Status: Unutilized
Comment: 3663 sq. ft., most recent use—admin., off-site use only

Bldg. T–415
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840153
Status: Unutilized
Comment: 1676 sq. ft., most recent use—HQ bldg., off-site use only

Bldg. T–530
Fort Drum Co: Jefferson NY 13602–

Landholding Agency: Army
Property Number: 219840154
Status: Unutilized
Comment: 2588 sq. ft., most recent use—HQ bldg., off-site use only

Bldg. T–840
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840155
Status: Unutilized
Comment: 2803 sq. ft., most recent use—dining, off-site use only

Bldg. T–892
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840156
Status: Unutilized
Comment: 2740 sq. ft., most recent use—HQ bldg., off-site use only

Bldg. T–991
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840157
Status: Unutilized
Comment: 2740 sq. ft., most recent use—HQ bldg., off-site use only

Bldg. T–996
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840158
Status: Unutilized
Comment: 9602 sq. ft., most recent use—storage, off-site use only

Bldg. S–998
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840159
Status: Unutilized
Comment: 1432 sq. ft., most recent use—storage, off-site use only

Bldg. T–2159
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840160
Status: Unutilized
Comment: 1948 sq. ft., off-site use only

Bldg. T–2339
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840163
Status: Unutilized
Comment: 2027 sq. ft., most recent use—museum, off-site use only

Bldg. P–2415
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840164
Status: Unutilized
Comment: 214 sq. ft., most recent use—incinerator, off-site use only

Bldg. T–2442
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840165
Status: Unutilized
Comment: 4340 sq. ft., most recent use—vet facility, off-site use only

Bldg. P–2443
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840166
Status: Unutilized
Comment: 793 sq. ft., most recent use—vet facility, off-site use only

Bldg. T–21572
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840167
Status: Unutilized
Comment: 240 sq. ft., most recent use—bunker, off-site use only

North Dakota

Bldg. 405
Stanley R. Mickelsen Safeguard Complex
Nekoma Co: Cavalier ND 58355–
Landholding Agency: Army
Property Number: 219840168
Status: Unutilized
Comment: 520 sq. ft., concrete block, most recent use—fuel oil pumping facility, off-site use only

Texas

Bldg. P–1374
Fort Sam Houston
San Antonio Co: Bexar TX 78234–5000
Landholding Agency: Army
Property Number: 219840169
Status: Unutilized
Comment: 111,448 sq. ft., presence of asbestos/lead paint, hazard abatement responsibility, most recent use—barracks, off-site use only

Bldg. P–1980
Fort Sam Houston
San Antonio Co: Bexar TX 78234–5000
Landholding Agency: Army
Property Number: 219840170
Status: Unutilized
Comment: 2989 sq. ft., presence of asbestos/lead paint, hazard abatement responsibility, most recent use—radio system station, off-site use only

Bldg. P–1981
Fort Sam Houston
San Antonio Co: Bexar TX 78234–5000
Landholding Agency: Army
Property Number: 219840171
Status: Unutilized
Comment: 200 sq. ft., presence of asbestos/lead paint, hazard abatement responsibility, most recent use—generator plant, off-site use only

Bldg. P–2396
Fort Sam Houston
San Antonio Co: Bexar TX 78234–5000
Landholding Agency: Army
Property Number: 219840172
Status: Unutilized
Comment: 1080 sq. ft., presence of asbestos, hazard abatement responsibility, most recent use—generator plant, off-site use only

Bldg. P–4226
Fort Sam Houston
San Antonio Co: Bexar TX 78234–5000
Landholding Agency: Army
Property Number: 219840173
Status: Unutilized
Comment: 1809 sq. ft., presence of lead paint, hazard abatement responsibility, most recent use—storage, off-site use only

Bldg. T–5123
Fort Sam Houston
San Antonio Co: Bexar TX 78234–5000
Landholding Agency: Army
Property Number: 219840174
Status: Unutilized
Comment: 2596 sq. ft., presence of asbestos/lead paint, hazard abatement responsibility, most recent use—admin., off-site use only

Bldg. 2840
Fort Hood
Ft. Hood TX 76544–
Landholding Agency: Army
Property Number: 219840175
Status: Unutilized
Comment: 2250 sq. ft., most recent use—admin., off-site use only

Bldg. 2841
Fort Hood
Ft. Hood TX 76544–
Landholding Agency: Army
Property Number: 219840176
Status: Unutilized
Comment: 2220 sq. ft., most recent use—storage, off-site use only

Bldg. 2842
Fort Hood
Ft. Hood TX 76544–
Landholding Agency: Army
Property Number: 219840177
Status: Unutilized
Comment: 2650 sq. ft., most recent use—admin., off-site use only

Bldg. 2843
Fort Hood
Ft. Hood TX 76544–
Landholding Agency: Army
Property Number: 219840178
Status: Unutilized
Comment: 8043 sq. ft., most recent use—admin., off-site use only

Bldg. 2844
Fort Hood
Ft. Hood TX 76544–
Landholding Agency: Army
Property Number: 219840179
Status: Unutilized
Comment: 8043 sq. ft., most recent use—admin., off-site use only

Bldg. 2845
Fort Hood
Ft. Hood TX 76544–
Landholding Agency: Army
Property Number: 219840180
Status: Unutilized
Comment: 8043 sq. ft., most recent use—admin., off-site use only

Bldg. 2846
Fort Hood
Ft. Hood TX 76544–
Landholding Agency: Army
Property Number: 219840181
Status: Unutilized
Comment: 8043 sq. ft., most recent use—admin., off-site use only

Washington

Bldg. A0220
Fort Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219840182
Status: Unutilized
Comment: 2284 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—recreation, off-site use only

Bldg. 4540
Fort Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219840183
Status: Unutilized

Comment: 1200 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—office, off-site use only

Bldg. 4541
Fort Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219840184
Status: Unutilized
Comment: 880 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—storage, off-site use only

Bldg. 4542
Fort Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219840185
Status: Unutilized
Comment: 112 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—heat plant, off-site use only

Bldg. 4549
Fort Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219840186
Status: Unutilized
Comment: 26220 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—green house heat plant, off-site use only

Bldg. 6118
Fort Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219840187
Status: Unutilized
Comment: 2263 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—classroom, off-site use only

Bldg. 6191
Fort Lewis Co: Pierce WA 98433–
Landholding Agency: Army
Property Number: 219840188
Status: Unutilized
Comment: 3663 sq. ft., needs rehab, presence of asbestos/lead paint, most recent use—post exchange, off-site use only

Land (by State)

Tennessee

Railroad Bed
Fort Campbell
Jack Miller Blvd.
Clarksville TN
Landholding Agency: Army
Property Number: 219840189
Status: Unutilized
Comment: approx. 6.06 acres

Suitable/Unavailable Properties

Buildings (by State)

New York

Bldg. T–2215
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840161
Status: Unutilized
Comment: 7670 sq. ft., most recent use—quarters, off-site use only

Bldg. T–2216
Fort Drum Co: Jefferson NY 13602–
Landholding Agency: Army
Property Number: 219840162
Status: Unutilized
Comment: 7670 sq. ft., most recent use—quarters, off-site use only

Unsuitable Properties

Buildings (by State)

Idaho

5 Bldgs.
Idaho Natl Engineering & Environmental Lab
CPP601, CPP603/648, CPP627, CPP633, CPP640
Scoville Co: Butte ID 83415–
Landholding Agency: Energy
Property Number: 419840002
Status: Unutilized
Reason: Within 2000 ft. of flammable or explosive material Secured Area

North Carolina

Bldg. 908
Marine Corps Base
Camp Lejeune Co: Onslow NC 28542–0004
Landholding Agency: Navy
Property Number: 779840021
Status: Unutilized
Reason: Secured Area; Extensive deterioration

Tennessee

11 Bldgs.
Naval Surface Warfare Center
Carderock Division, Detachment Memphis
Memphis Co: Shelby TN 38113–
Landholding Agency: Navy
Property Number: 779840022
Status: Unutilized
Reason: Secured Area

[FR Doc. 98–30718 Filed 11–19–98; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Office of the Secretary

Notice of Renewal of the Public Advisory Group Charter—EXXON VALDEZ Oil Spill

AGENCY: Department of the Interior, Office of the Secretary.

SUMMARY: This notice is published in accordance with 41 CFR Part 101–6, section 101–6.1015(a), Committee establishment, reestablishment, or renewal. Following the recommendation and approval of the EXXON VALDEZ Oil Spill Trustee Council, the Secretary of the Interior hereby renews the Exxon Valdez Oil Spill Public Advisory Group Charter to continue for two years.

FOR FURTHER INFORMATION CONTACT: Douglas Mutter, Department of the Interior, Office of Environmental Policy and Compliance, 1689 ''C'' Street, Suite 119, Anchorage, Alaska, (907) 271–5011.

SUPPLEMENTARY INFORMATION: On March 24, 1989, the T/V EXXON VALDEZ ran aground on Bligh Reef in Prince William Sound in Alaska spilling approximately 11 million gallons of North Slope crude oil. Oil moved into the Gulf of Alaska, along the Kenai coast to Kodiak Island and the Alaska Peninsula—some 600 miles from Bligh Reef. Massive clean-up and containment efforts were initiated and continued to 1992. On October 8, 1991, an agreement was approved by the United States District Court for the District of Alaska that settled claims of the United States and the State of Alaska against the Exxon Corporation and the Exxon Shipping Company for various criminal and civil violations.

Under the civil settlement, Exxon companies agreed to pay to the governments $900 million over a period of 10 years.

The EXXON VALDEZ Oil Spill Trustee Council was established to manage the funds obtained from the civil settlement of the EXXON VALDEZ Oil Spill. The Trustee Council is composed of three State of Alaska trustees (Attorney General; Commissioner, Department of Environmental Conservation; and Commissioner, Department of Fish and Game) and three Federal representatives appointed by the Federal Trustees (Secretary, U.S. Department of Agriculture; the Administrator of the National Oceanic and Atmospheric Administration; and the Secretary, U.S. Department of the Interior).

The Public Advisory Group was created by Paragraph V.A.4 of the Memorandum of Agreement and Consent Decree entered into by the United States of America and the State of Alaska on August 27, 1991 and approved by the United States District Court for the District of Alaska in settlement of *United States of America* v. *State of Alaska*, Civil Action No. A91–081 CV. The Public Advisory Group was chartered by the Secretary of the Interior on October 23, 1992 and functions solely as an advisory body, and in compliance with the provisons of the Federal Advisory Committee Act (5 U.S.C. App. (1988)).

The Public Advisory Group was established to advise the Trustee Council, and began functioning in October 1992. The Public Advisory Group consists of 17 members representing the following principal interests: sport hunting and fishing, environmental, public-at-large (5), recreation users, local government, science/academic, conservation, subsistence, commercial fishing, aquaculture, commercial tourism, forest products, and Native landowners. Members were appointed to serve a two-year term.

To carry out its advisory role, the Public Advisory Group makes recommendations to, and advises, the Trustee Council in Alaska on the following matters:

All decisions related to injury assessment, restoration activities, or other use of natural resource damage recovery monies obtained by the governments, including all decisions regarding:

a. Planning, evaluation and allocation of available funds;

b. Planning, evaluation and conduct of injury assessment; and

c. Planning, evaluation and conduct of restoration activities.

Trustee Council intentions regarding the importance of obtaining a diversity of viewpoints is stated in the *Public Advisory Group Background and Guidelines* (March 1993, updated June 1994 and August 1996): ''The Trustee Council intends that the Public Advisory Group be established as an important component of the Council's public involvement process.'' The Council continues, stating their desire that ''* * * a wide spectrum of views and interest are available for the Council to consider as it evaluates, develops, and implements restoration activities. It is the Council's intent that the diversity of interests and views held by the Public Advisory Group members contribute to wide ranging discussions that will be of benefit to the Trustee Council.''

In order to ensure that a broad range of public viewpoints continues to be available to the Trustee Council, and in keeping with the settlement agreement, the continuation of the Public Advisory Group for another two-year period is recommended.

Dated: November 6, 1998.

Bruce Babbitt,

Secretary of the Interior.

[FR Doc. 98–30994 Filed 11–19–98; 8:45 am]

BILLING CODE 4310–RG–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of an Environmental Assessment, Finding of No Significant Impact, and Receipt of an Application for an Incidental Take Permit for a 48-Acre Mixed Residential/Commercial Development Project, in Volusia County, Florida

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: Mortgage Management, L. P. of Chattanooga, Tennessee (Applicant), is seeking an incidental take permit (ITP) from the Fish and Wildlife Service (Service), pursuant to Section 10(a)(1)(B) of the Endangered Species Act of 1973 (Act), as amended. The ITP would authorize the take of one family of the threatened Florida scrub-jay, *Aphelocoma coerulescens* and the threatened Eastern indigo snake, *Drymarchon corais couperi,* in Volusia County, Florida, for a period of ten (10) years. The proposed taking is incidental to land clearing activities and mixed residential/commercial development on a 48-acre project site (Project). The Project contains about 8.2 acres of occupied Florida scrub-jay habitat, and the potential exists for the entire Project to provide habitat to the Eastern indigo snake. A description of the mitigation and minimization measures outlined the Applicant's Habitat Conservation Plan (HCP) to address the effects of the Project to the protected species is as described further in the **SUPPLEMENTARY INFORMATION** section below.

The Service also announces the availability of an environmental assessment (EA) and HCP for the incidental take application. Copies of the EA and/or HCP may be obtained by making a request to the Regional Office (see **ADDRESSES**). Requests must be in writing to be processed. This notice also advises the public that the Service has made a preliminary determination that issuing the ITP is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), as amended. The Finding of No Significant Impact (FONSI) is based on information contained in the EA and HCP. The final determination will be made no sooner than 30 days from the date of this notice. This notice is provided pursuant to Section 10 of the Act and NEPA regulations (40 CFR 1506.6).

The Service specifically requests information, views, opinions from the public via this Notice, including the identification of any other aspects of the human environment not already identified in the Service's EA. Further, the Service is specifically soliciting information regarding the adequacy of the HCP as measured against the Service's ITP issuance criteria found in 50 CFR Parts 13 and 17.

DATES: Written comments on the permit application, EA, and HCP should be sent to the Service's Regional Office (see **ADDRESSES**) and should be received on or before December 21, 1998.

ADDRESSES: Persons wishing to review the application, HCP, and EA may obtain a copy by writing the Service's Southeast Regional Office, Atlanta, Georgia. Documents will also be available for public inspection by appointment during normal business hours at the Regional Office, 1875 Century Boulevard, Suite 200, Atlanta, Georgia 30345 (Attn: Endangered Species Permits), or Field Supervisor, U.S. Fish and Wildlife Service, 6620 Southpoint Drive, South, Suite 310, Jacksonville, Florida 32216–0912. Written data or comments concerning the application, EA, or HCP should be submitted to the Regional Office. Requests for the documentation must be in writing to be processed. Comments must be submitted in writing to be processed. Please reference permit number PRT–TE004632–0 in such comments, or in requests of the documents discussed herein.

FOR FURTHER INFORMATION CONTACT: Mr. Rick G. Gooch, Regional Permit Coordinator, (see **ADDRESSES** above), telephone: 404/679–7110, facsimile: 404/679–7081; or Mr. Jay B. Herrington, Fish and Wildlife Biologist, Jacksonville Field Office, (see **ADDRESSES** above), telephone: 904/232–2580, extension 120.

SUPPLEMENTARY INFORMATION:

Aphelocoma coerulescens is geographically isolated from other subspecies of scrub-jays found in Mexico and the Western United States. The Florida scrub-jay is found almost exclusively in peninsular Florida and is restricted to scrub habitat. The total estimated population is between 7,000 and 11,000 individuals. Due to habitat loss and degradation throughout the State of Florida, it has been estimated that the Florida scrub-jay population has been reduced by at least half in the last 100 years. Surveys have indicated that one family of Florida scrub-jays inhabit the Project site. Construction of the Project's infrastructure, commercial construction and construction of the individual home sites will likely result in death of, or injury to, *Aphelocoma coerulescens* incidental to the carrying out of these otherwise lawful activities. Habitat alteration associated with property development will reduce the availability of feeding, shelter, and nesting habitat.

The Eastern Indigo snake (*Drymarchon corais couperi*) is the longest north American snake, is reclusive, ranges up to 250 acres in the summer and down to less than 25 acres in the winter. Historical distribution is largely uncertain; however, records reflect distribution throughout the Florida peninsula as well as occurrence in the panhandle and Georgia. It is known to frequent dry, upland habitats with nearby wetlands. Destruction of suitable habitat for agriculture, livestock, forestry and development of commercial/residential properties as

well as commercial exploitation (collecting) and ''gassing'' are well documented as diminishing the population to a suggested viable presence only in the states of Florida and Georgia. The acquisition, preservation and management of large tracts of suitable habitat as opposed to small, isolated parcels is generally recommended.

Although not observed on site, the Applicant has requested authorization for incidental take of any Eastern Indigo snake occurring within the tract. In addition to the normal species specific precautionary and educational materials to be provided to on site personnel for the Eastern Indigo snake as outlined in the HCP, the mitigation strategy as identified above for the Florida scrub jay will be applied to offset unavoidable impacts to the Eastern Indigo snake.

The EA considers the environmental consequences of three alternatives. The no action alternative may result in loss of habitat for *Aphelocoma coerulescens* and exposure of the Applicant under Section 9 of the Act. The on-site preservation alternative would preserve 8.2 acres of occupied habitat. This option would not require an ITP, however, the portion of commercially developable property would be reduced from 11 acres to 2.8 acres. In addition, this option would not provide any management for the Florida scrub-jay family currently located on the property. The third alternative, the off-site mitigation alternative, would provide funds to the National Fish and Wildlife Foundation Fund for the Conservation of the Florida Scrub-jay to procure occupied Florida scrub-jay habitat in Volusia County, Florida to be managed into perpetuity. The proposed action alternative is issuance of the ITP with off-site mitigation. The affirmative conservation measures outlined in the HCP to be employed to offset the anticipated level of incidental take to the protected species are the following:

1. To mitigate for the up to 8.2 acres of occupied habitat that would be eliminated on site the applicant will provide funds to the National Fish and Wildlife Foundation in the amount of $103,320.00 to be spent for procurement of occupied Florida scrub-jay habitat and conservation in Volusia County at a later date. This amount is based on mitigation at a ratio of 2:1 (two acres purchased for every one acre impacted and land costs of $5,000 per acre), a $1,000 per acre management endowment, and an administrative fee of five percent of the total cost for management of the National Fish and Wildlife Foundation Fund for conservation of the Florida scrub-jay.

Upon procurement, the mitigation land would first be donated to and subsequently managed by a holding company. After initial habitat restoration, the property would then be conveyed to Volusia County or other acceptable land conservation program, along with a conservation easement, requiring preservation and management for Florida scrub-jays (and eastern indigo snakes) into perpetuity.

2. No clearing of scrub vegetation would occur during the nesting season of the Florida scrub jay.

3. The HCP provides a funding mechanism for these mitigation measures.

As stated above, the Service has made a preliminary determination that the issuance of the ITP is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of NEPA. This preliminary information may be revised due to public comment received in response to this notice and is based on information contained in the EA and HCP.

An appropriate excerpt from the FONSI reflecting the Service's finding on the application is provided below:

Based on the analysis conducted by the Service, it has been determined that:

1. Issuance of an ITP would not have significant effects on the human environment in the project area.

2. The proposed take is incidental to an otherwise lawful activity.

3. The Applicant has ensured that adequate funding will be provided to implement the measures proposed in the submitted HCP.

4. Other than impacts to endangered and threatened species as outlined in the documentation of this decision, the indirect impacts which may result from issuance of the ITP are addressed by other regulations and statutes under the jurisdiction of other government entities. The validity of the Service's ITP is contingent upon the Applicant's compliance with the terms of the permit and all other laws and regulations under the control of State, local, and other Federal governmental entities.

The Service will also evaluate whether the issuance of a Section 10(a)(1)(B) ITP complies with Section 7 of the Act by conducting an intra-Service Section 7 consultation. The results of the biological opinion, in combination with the above findings, will be used in the final analysis to determine whether or not to issue the ITP.

Dated: November 4, 1998.

Sam D. Hamilton,

Regional Director.

[FR Doc. 98–30346 Filed 11–19–98; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MT–951–99–1020–00]

Call for Nominations for Butte Resource Advisory Council

AGENCY: Bureau of Land Management, DOI.

ACTION: Notice.

SUMMARY: The purpose of this notice is to solicit public nominations for the Elected Official position on the Butte Resource Advisory Council (RAC). The term of the position will expire in September 1999. RACs provide advice and recommendations to the Bureau of Land Management (BLM) on land use planning and management of the public lands within their geographic areas. Public nominations will be considered for 45 days after the publication date of this notice.

The Federal Land Policy and Management Act directs the Secretary of the Interior to involve the public in the planning and management of the public lands administered by the BLM. Each Council has 15 members who serve staggered terms. RAC membership must reflect a balanced representation of the various interests and users of the public lands. These include persons who are representatives of the following categories:

Category One—Holders of federal grazing permits and representatives of energy and mining development, timber industry, off-road vehicle use, and developed recreation.

Category Two—Representatives of environmental and resource conservation organizations, archaeological and historic interests, and wild horse and burro groups;

Category Three—Representatives of State, county and local government, Native American tribes, academicians involved in natural sciences, and the public at large.

At least one member of the RAC must be an elected official of general purpose government serving the people within the geographic area the RAC represents.

Nominees will be evaluated based on their education, training, and experience of the issues and knowledge of the geographical area of the RAC. Nominees should have demonstrated a

commitment to collaborative resource decision-making.

Individuals may nominate themselves or others. Nominees must be residents of Montana. Nominees will be evaluated based on their education, training, and experience of the issues and knowledge of the geographical area of the RAC. All nominations must be accompanied by letters of reference from represented interests or organizations, a completed background information nomination form, as well as any other information that speaks to the nominee's qualifications.

DATES: All nominations should be received by the BLM Butte Field Office by January 4, 1999.

FOR FURTHER INFORMATION CONTACT: Jeanne Sullivan, BLM Butte Field Office, 106 North Parkmont, P.O. Box 3388, Butte, Montana 59701; telephone 406–494–5059.

Dated: November 12, 1998.

Gary Gerth,

Assistant Field Manager.

[FR Doc. 98–30968 Filed 11–19–98; 8:45 am]

BILLING CODE 4310–DN–M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–330–4210–05, CACA 39081]

Notice of Realty Action; Recreation and Public Purposes (R&PP) Act Classification, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action.

SUMMARY: The following public land in Humboldt County, California, has been examined and found suitable for classification for transfer to the State of California under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869, *et seq.*). The State of California proposes to incorporate the land into Richardson Grove State Park and manage them under plans approved for that park.

Humboldt Base & Meridian

T.5S., R.3E.,

Section 11, SWSW.

Containing 40 acres, more or less.

The land is not needed for Federal purposes. Transfer is consistent with current BLM land use planning and would be in the public interest.

The patent, when issued, will be subject to the following terms:

1. Provisions of the Recreation and Public Purposes Act and to all applicable regulations of the Secretary of the Interior.

2. A right-of-way for ditches and canals constructed by the authority of the United States.

3. All minerals shall be reserved to the United States, together with the right to prospect for, mine and remove the minerals.

4. Those rights for ingress/egress and timber hauling granted to Coombs Tree Farms under Right-of-Way CACA 39081.

Detailed information concerning this action is available for review at the Arcata Field Office, 1695 Heindon Road, Arcata, CA 95521. Upon publication of this notice in the **Federal Register**, the land will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for transfer under the Recreation and Public Purposes Act and leasing under the mineral leasing laws. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested persons may submit comments regarding the proposed transfer or classification of the land to Lynda J. Roush, Field Manager, 1695 Heindon Road, Arcata, CA 95521.

Classification Comments

Interested parties may submit comments involving the suitability of the land for inclusion into Richardson's Grove State Park. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

Application Comments

Interested parties may submit comments regarding the specific proposed action in the application, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land for inclusion into Richardson's Grove State Park. Comments received on the classification will be answered by the State Director with the right to further comment to the Secretary. Comments on the application will be answered by the State Director with the right of appeal to the IBLA.

Lynda J. Roush,

Arcata Field Manager.

[FR Doc. 98–30914 Filed 11–19–98; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–180–09–1430–01: SAC 079371]

Realty Action, Recreation and Public Purposes (R&PP) Act Classification; Placer County, California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Realty Action—Recreation and Public Purposes (R&PP) Act Classification; Placer County, California.

SUMMARY: The following public lands in Placer County, California have been examined and found suitable for classification for conveyance to the Placer County Board of Supervisors under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*). The Placer County Board of Supervisors currently leases the following lands for a transfer station.

Mount Diablo Meridian, California

T. 13 N., R. 10 E.,
Sec. 3, lots 19 & 20. (Foresthill)
Containing 52.15 acres, more or less.

The lands are not needed for Federal purposes. Conveyance is consistent with the current BLM land use planning and would be in the public interest.

The patent, when issued, will be subject to the following terms, conditions, and reservations:

1. Provisions of the Recreation and Public Purposes Act and to all applicable regulations of the Secretary of the Interior.

2. A right-of-way for ditches and canals constructed by the authority of the United States.

3. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove materials.

4. An easement for streets, roads, and utilities in accordance with the transportation plan for each County.

Detailed information concerning this action is available for review at the office of the Bureau of Land Management, Folsom Field Office, 63 Natoma Street, Folsom, California.

Upon publication of this notice in the **Federal Register**, the lands will be segregated from all forms of appropriation under the public land laws, including the general mining laws, except for conveyance under the Recreation and Public Purposes Act and leasing under the mineral leasing laws. For a period of 45 days from the date of publication of this notice in the **Federal Register**, interested persons may submit

comments regarding the proposed conveyance or classification of the lands to the Field Manager, Folsom Field Office, 63 Natoma Street, Folsom, CA 95630.

Classification Comments

Interested parties may submit comments involving the suitability of the lands. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with the local planning and zoning, or if the use is consistent with the State and Federal programs.

Application Comments

Interested parties may submit comments regarding the specific use proposed in the applications and plan of developments, whether the BLM followed proper administrative procedures in reaching the decision, or any other factor not directly related to the suitability of the land.

Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the classification will become effective 60 days from the date of publication of this notice in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Karen Montgomery, BLM Folsom Field Office, (916) 985–4474.

D.K. Swickard,

Field Manager.

[FR Doc. 98–31053 Filed 11–19–98; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as Amended

In accordance with Department of Justice policy, 28 CFR 50.7, notice is hereby given that a proposed consent decree in the action entitled *United States of America* v. *AlliedSignal Inc. and Amphenol Corporation,* Civil Action No. 97–CV–0436 (TJM/DNH) (N.D.N.Y.), was lodged on November 3, 1998 with the United States District Court for the Northern District of New York. The proposed consent decree resolves potential claims of the United States, on behalf of the U.S. Environmental Protection Agency, against third-party defendants the Village of Sidney, New York, and the Towns of Sidney, Masonville, and Tompkins, New York, under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, 42 U.S.C. 9601–9675. These claims are for recovery of response costs incurred and to be incurred by the United States in connection with the Sidney Landfill Superfund Site (''Site''), located in Delaware County, New York.

Under the terms of the proposed consent decree, the Village of Sidney will pay $46,597.60, the Town of Sidney will pay $10,812.00, the Town of Masonville will pay $3,696.75, and the Town of Tompkins will pay $1,762.25 to the United States in reimbursement of response costs incurred and to be incurred by the United States with respect to the Site.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, Washington, DC 20530, and should refer to *United States* v. *AlliedSignal Inc. and Amphenol Corporation,* Civil Action No. 97–CV–0436 (TJM/DNH) (N.D.N.Y.), DOJ Ref. No. 90–11–2–1128C.

The proposed consent decree may be examined at the Office of the United States Attorney, 445 Broadway, Room 231, Albany, New York 12207; the Region II Office of the Environmental Protection Agency, 290 Broadway, New York, New York 10007–1866; and the Consent Decree Library, 1120 G Street, NW., 3rd Floor, Washington, DC 20005, telephone (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $7.25 (25 cents per page reproduction costs) made payable to Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–31002 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that a proposed consent decree in *United States* v. *Ben Shemper & Sons, Inc., et al.,* Civil Action No. 94–50385/LAC was lodged on October 30, 1998 with the United States District Court for the Northern District of Florida. In December, 1994, the United States filed this action pursuant to section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9607, to recover response costs incurred by EPA at the Sapp Battery Site near Cottondale, Florida. The site was contaminated with lead and other heavy metals as the result of battery cracking operations conducted at the site from approximately 1970 to 1980. The consent decree requires the settlors to pay the following amounts: Gulf Coast Recycling, Inc.—$612,000; Southern Scrap Company, Inc.—$205,000; Taracorp, Inc.—$309,000; and Dynamic Metals, Inc.—$75,000.

The Department of Justice will receive, for a period of 30 days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environmental and Natural Resources Division, Department of Justice, Washington, DC., 20530, and should refer to: *United States* v. *Ben Shemper & Sons, Inc., et al.,* DOJ Ref. #90–11–2–699E.

The proposed consent decree may be examined at the Office of the United States Attorney, Northern District of Florida, 114 E. Gregory Street, Pensacola, Florida 32501; Office of the U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street, SW., Atlanta, Georgia 30303; and at the Consent Decree Library, 1120 G Street, NW., 3rd Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street NW., 3rd Floor, Washington, DC 20005. In requesting a copy, please refer to the referenced case and enclose a check in the amount of $5.50 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Walker Smith,

Deputy Chief, Environmental Enforcement Section, Environmental and Natural Resources Division.

[FR Doc. 98–31001 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation, and Liability Act

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States* v. *Chrysler Corporation, Allied Waste Systems, Inc., Allied Services, LLC, and Clarence J. and Evelyn K. Chott*, No. 4:98CV01809CAS (E.D. Missouri), was lodged on October 28, 1998, with the United States District Court for the Eastern District of Iowa. With regard to the Defendants, the Consent Decree resolves claims filed by the United States on behalf of the United States Environmental Protection Agency (''EPA'') pursuant to the Comprehensive Environmental Response, Compensation and Liability Act, *as amended*, 42 U.S.C. 9601, *et seq.*

The United States entered into the Consent Decree in connection with the Fenton Creek Dump Site located in Fenton, Missouri. The Consent Decree provides that the Settling Defendants will reimburse the United States a total of $2,550,000 for costs incurred and to be incurred by the United States at the Site. The Settling Defendants also will pay $52,126 for natural resource damages at the Site.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Chrylser Corporation, Allied Waste Systems, Inc., Allied Services, LLC, and Clarence J. and Evelyn K. Chott*, DOJ Reg. #90–11–2–1288.

The proposed Consent Decree may be examined at the Office of the United States Attorney, 1114 Market Street, Room 401, St. Louis, Missouri 63101; the Region 7 Office of the Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, Kansas; and at the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005. In requesting a copy refer to the referenced case and enclose a check in the amount of $7.50 (25 cents per page reproduction costs), payable to the Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section.

[FR Doc. 98–31000 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Clean Air Act and the National Emissions Standards for Hazardous Air Pollutants for Asbestos

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States of America* v. *City of Rolla, et al.* Civil Action No. 2:98CV00061DJS, was lodged on October 19, 1998 with the United States District Court for the Eastern District of Missouri.

The Consent Decree settles civil penalty and injunctive claims asserted against the City of Rolla, Missouri (''the City'') and Don Maggi, Inc. (''Don Maggi'') under the Clean Air Act, 42 U.S.C. 7412 and the National Emission Standards for Hazardous Air Pollutants for asbestos, 40 CFR part 61, subpart M. The Complaint alleges that in the course of the March of 1995 demolition of a City-owned building known as the ''Old Police Station,'' the City and its demolition contractor, Don Maggi, violated the notice and inspection requirements of the asbestos NESHAP, 40 CFR 61.145(a) and (b).

The Consent Decree settles all the claims asserted in the Complaint. It provides that the City and Don Maggi will pay civil penalties of $24,700 and $22,000 respectively and also requires them to undertake an asbestos training and monitoring program.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, PO Box 7611, Ben Franklin Station, Washington, DC 20044. Comments should refer to *United States of America* v. *City of Rolla, et al.*, DOJ Ref. No. 90–5–21–2190.

The proposed consent decree may be examined at the office of the United States Attorney, Eastern District of Missouri, 1114 Market Street, St. Louis, MO 63101; the Region VII Office of the Environmental Protection Agency, 726 Minnesota Avenue, Kansas City, KS 66101; and at the Consent Decree Library, 1120 G Street, NW., 3rd Floor, Washington, DC 20005, (202) 624–0892. A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library.

In requesting a copy, please enclose a check in the amount of $8.50 (25 cents per page reproduction cost) payable to the ''Consent Decree Library.''

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–31005 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to Comprehensive Environmental Response, Compensation, and Liability Act

Notice is hereby given that on November 6, 1998, a proposed consent decree in *United States* v. *Compaction Systems Corporation, et al.*, Civil Action No. 96–5349, was lodged with the United States District Court for the District of New Jersey.

In this action, the United States alleged, *inter alia*, that under section 107 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), 42 U.S.C. 9607, the defendants were liable for the federal government's costs in responding to the release or threatened release of hazardous substances at the Combe Fill North Landfill Superfund Site in Mount Olive, Morris Township, New Jersey (the Site). The proposed consent decree resolves the United States' claim for past response costs against the defendants and third-party defendants named in this action, including, among others, Occidental Chemical Corporation, Connecticut Resource Recovery Authority, Rayonier, Inc., Knoll Pharmaceuticals, Inc., and Browning-Ferris Industries of North Jersey, Inc. (A complete list of current settling parties is contained in the proposed decree; during the period of public comment, other parties may be added to that list.) Under the terms of the proposed consent decree, the settling parties will pay the United States the sum of $7.5 million in reimbursement of past response costs with respect to the Site.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the proposed partial consent decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice,

Washington, DC 20530, and should refer to *United States* v. *Compaction Systems Corporation, et al.*, Civil Action No. 99–5349, D.J. Ref. 90–11–2–1134.

The proposed consent decree may be examined at the Office of the United States Attorney, District of New Jersey, 970 Broad Street, Newark, New Jersey 07102, at U.S. Environmental Protection Agency Region II, 290 Broadway, New York, New York 10007–1866, and at the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 4th Floor, Washington, DC 20005. In requesting a copy, please enclose a check in the amount of $17.25 (25 cent per page reproduction cost).

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–31003 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Joint Motion for Modification of Amended Consent Decree, Which Resolved Action Under the Clean Air Act

In accordance with Departmental policy, 28 CFR 50.7, please be advised that a proposed Joint Motion for Modification of Amended Consent Decree was lodged on November 9, 1998, in *United States* v. *Ohio Power Company*, C.A. No. 5:94–CV–100 (N.D.WVa), with the United States District Court for the Northern District of West Virginia (''District Court''). The Joint Motion extends a deadline of November 1, 1998, contained in the Amended Consent Decree. That deadline sets forth the date by which defendant must come into compliance at its Kammer power plant in Marshall County, West Virginia, with the sulfur dioxide limitation presently contained in the West Virginia State Implementation Plan (''SIP''), in the event that the State does not submit a revised SIP by October 1, 1999. Should the State fail to submit the SIP by that date, defendant must comply with the current sulfur dioxide limitation by December 31, 1999. The Amended Consent Decree resolved an action which the United States brought in 1994 against Ohio Power under section 113 of the Clean Air Act, 42 U.S.C. 7413.

Any comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *United States* v. *Ohio Power Company*, DOJ Ref. #90–5–2–1–1958. The proposed Joint Motion may be examined at the Office of the United States Attorney, 1100 Main Street, Room 200, Wheeling, West Virginia 26003, and the Region III Office of the Environmental Protection Agency, 1650 Arch Street, Philadelphia, Pennsylvania 19103. A copy of the proposed Joint Motion may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 4th Floor, Washington, DC 20005, (202) 624–0892. The proposed Joint Motion contains 74 pages, including attachments. To obtain the Joint Motion, with attachments, please enclose a check for $18.50. Please make the check payable to the Consent Decree Library, and refer to the case by its title and DOJ Ref. #90–5–2–1–1958.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–30998 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–01–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act, (''CERCLA''), 42 U.S.C. 9601 et seq.

Under 28 CFR 50.7, notice is hereby given that on September 25, 1998, a proposed Consent Decree in *United States* v. *United Technologies Automotive Systems, Inc., et al.*, Civil Action No. 8–98–CV–90150, was lodged with the United States District Court for the Southern District of Iowa.

In this action against United Technologies Automotive Systems, Inc, (''UTAS''), F/K/A Sheller-Globe Corporation (''Sheller-Globe'') and David B. and Miriam Grimes (the ''Grimes''), pursuant to sections 106 and 107 of CERCLA, 42 U.S.C. 9606 and 9607, on behalf of the United States Environmental Protection Agency (''EPA''), the United States sought: (1) Reimbursement of costs incurred in performing response activities at the Sheller-Globe Superfund Site in Keokuk, Iowa (''Site'') and (2) performance of response work by the defendants at the Site pursuant to the Record of Decision, dated September 20, 1995 (''ROD''). Under the Consent Decree, the defendants will reimburse the EPA Hazardous Substance Superfund approximately $35,000 for all response costs incurred between the date of the ROD and the effective date of the Consent Decree, and all future costs incurred by the Department of Justice (''DOJ'') and EPA. The defendants also will provide access and institutional controls and perform the remedial work in accordance with the Consent Decree, ROD, and Statement of Work (''SOW''), valued at approximately $121,000. This settlement, together with a prior Administrative Order on Consent, (''AOC'') entered into by EPA and UTAS predecessor Sheller-Globe on October 23, 1990, in which Sheller-Globe agreed to pay EPA's past costs at or in connection with the Site as well as the costs incurred by EPA associated with the oversight of the AOC, will result in a recovery of 100% of the United States' expected response costs. In exchange, UTAS and the Grimes will receive a covenant not to sue pursuant to sections 106 and 107(a) of CERCLA, 42 U.S.C. 9606 and 9607(a), relating to the Site, subject to all standard reservations and reopeners. In addition, UTAS and the Grimes will receive contribution protection under section 113(f)(2) of CERCLA, 42 U.S.C. 9613(f)(2).

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments relating to the Consent Decree. Comments should be addressed to the Assistant Attorney General of the Environment and Natural Resources Division, Department of Justice, Washington, D.C. 20530, and should refer to *United States* v. *United Technologies Automotive Systems, Inc. et al.*, D.J. Ref. 90–11–2–1266.

The Consent Decree may be examined at the Office of the United States Attorney, Southern District of Iowa, 110 East Court Street, Des Moines, Iowa 50309, at U.S. EPA—Region VII, 726 Minnesota Avenue, Kansas City, Kansas 66101, and at the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005, (202) 624–0892. A copy of the Consent Decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW., 3rd Floor, Washington, D.C. 20005. In requesting a complete copy with all Attachments, please enclose a check in the amount of $69.75 (25 cents per page reproduction cost) payable to the Consent Decree Library. In requesting a copy of the Consent Decree without Attachments, please enclose a check in the amount of $23.25 (25 cents per page reproduction cost) payable to the Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–31004 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF JUSTICE

Notice of Lodging of Consent Decree Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with Departmental policy and section 122 of the Comprehensive Response, Compensation and Liability Act (''CERCLA''), 42 U.S.C. 9622, the Department of Justice gives notice that a proposed consent decree in *United States* v. *USX Corp., et al.*, Civil No. 98 C 6389 (N.D. Ill.), was lodged with the United States District Court for the Northern District of Illinois on November 5, 1998, pertaining to the Yeoman Creek Landfill Superfund Site (the ''Site''), located in Waukegan, Lake County, Illinois. The proposed consent decree would resolve the United States' civil claims against all twenty-one defendants named in the action as provided in the consent decree. The settling defendants are USX Corp.; Stone Container Corp.; Coral Chemical Co.; Victory Memorial Hospital Association; Franciscan Sisters Healthcare Corp.; The Copley Press, Inc.; North Chicago Refiners & Smelters, Inc. and R. Lavin & Sons, Inc.; North Shore Sanitary District; North Shore Printers, Inc.; Westvaco Corp.; Jensen Disposal, Inc.; Waukegan Park District; American National Bank & Trust Co. of Chicago, as successor Trustee to Bank of Ravenswood under Trust No. 25–9142, and the Terrace Nursing Home Limited Partnership and Beneficiary of Trust No. 25–9142; American National Bank & Trust Co. of Waukegan, as Trustee under Trust No. 2566, and John Zygokostas as Beneficiary of Trust No. 2566; Chicago Title and Trust Co., as Trustee under Trust Agreement Dated September 28, 1970, and Known as Trust No. 55858, and James E. Evoy, Paul E. Kamschulte, Jr., and Allan J. Jacobs as Beneficiaries; Sheldon Lovinger and Norman Kramer, jointly and as Beneficiaries of Grand National Bank Trust No. 1922; Grand Premier Trust and Investment, Inc., N.A. as successor Trustee to American National Bank & Trust Company of Waukegan under Trust Agreement dated December 28, 1977, and known as Trust No. 1455, and Chien-Huey Shih as Beneficiary of Trust No. 1455; Howard I. Bass, individually and d/b/a HIBCO Investments; Evoy, Kamschulte, Jacobs & Company, L.L.P.; The Terrace Nursing Home, Inc.; and Sunset House Restaurant, Inc. Under the proposed consent decree, the twenty-one settling defendants would pay a total of $1,585,990.00. Twenty of the settling defendants qualify as *de minimis* parties under CERCLA Section 122(g).

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resource Division, United States Department of Justice, Washington, DC 20530, and should refer to *United States* v. *USX Corp., et al.*, Civil No. 98 C 6389 (N.D. Ill.), and DOJ Reference No. 90–11–2–1315/1.

The proposed consent decree may be examined at: (1) The Office of the United States Attorney for the Northern District of Illinois, 219 S. Dearborn Street, Chicago, IL 60604; (2) the United States Environmental Protection Agency (Region 5), 77 West Jackson Boulevard, Chicago, Illinois 60604–3590 (contact Stuart Hersh (312–886–6235)); and (3) the U.S. Department of Justice, Environment and Natural Resources Division Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005 (202–624–0892). A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street, NW, 3rd Floor, Washington, DC 20005. In requesting a copy, please refer to the referenced case and DOJ Reference Number and enclose a check in the amount of $15.50 for the consent decree only (62 pages at 25 cents per page reproduction costs), or $17.25 for the consent decree and all appendices (69 pages), made payable to the Consent Decree Library.

Joel M. Gross,

Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 98–30999 Filed 11–19–98; 8:45 am]

BILLING CODE 4410–15–M

DEPARTMENT OF LABOR

Employment and Training Administration

Job Training Partnership Act: Indian and Native American Employment and Training Programs; List of Grantees Receiving Waivers of Competition for Program Year 1999

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: List of current JTPA section 401 grantees given waivers of competition for the Program Year (PY) 1999 designation period.

SUMMARY: Pursuant to the instructions and procedures published in the **Federal Register** notice of September 28, 1998 (63 FR 51771–51776), the Department of Labor hereby publishes a list of those current JTPA section 401 grantees receiving waivers of competition for Program Year 1999, pursuant to section 401(l) of the Job Training Partnership Act, as amended.

DATES: Final Notices of Intent must be postmarked no later than January 1, 1999.

ADDRESSES: Send an original and two copies of the Final Notices of Intent to Mr. Leroy Bingham, Chief, Division of Indian and Native American Programs, ATTN: Designation Desk, U.S. Department of Labor, Room N–4641 FPB, 200 Constitution Avenue, NW., Washington, DC 20210.

SUPPLEMENTARY INFORMATION: Grantees who receive waivers must still submit a Final Notice of Intent in accordance with the instructions as referenced above to be designated as a JTPA section 401 grantee for the PY 1999 Designation Period.

Indian and Native American Programs; JTPA, Section 401, Grantees; Waivers Granted for Program Year 1999

Alabama

Intertribal Council of Alabama
Poarch Band of Creek Indians

Alaska

Aleutian-Pribilof Islands Association
Association of Village Council Presidents
Bristol Bay Native Association
Central Council of Tlingit and Haida Indian Tribes of Alaska
Chugachmiut
Cook Inlet Tribal Council, Inc.
Kawerak, Incorporated
Kenaitze Indian Tribe
Kodiak Area Native Association
Maniilaq Manpower, Inc.
Metlakatla Indian Community
Native Village of Barrow
Orutsararmuit Native Council
Tanana Chiefs Conference, Inc.

Arizona

Affiliation of Arizona Indian Centers, Inc.
American Indian Association of Tucson
Colorado River Indian Tribes
Gila River Indian Community
Hopi Tribal Council
Inter-Tribal Council of Arizona, Inc.
Native Americans for Community Action, Inc.
The Navajo Nation
Pascua Yaqui Tribe
Phoenix Indian Center, Inc.
Quechan Indian Tribe
Salt River/Pima-Maricopa Indian Community
San Carlos Apache Tribe
Tohono O'Odham Nation
White Mountain Apache Tribe

Arkansas

American Indian Center of Arkansas, Inc.

California

California Indian Manpower Consortium
Candelaria American Indian Council
Indian Human Resources Center
Northern California Indian Development Council, Inc.
Southern California Indian Center, Inc.
Tule River Tribe
United Indian Nations, Inc.
Ya-Ka-Ama Indian Education & Development

Colorado

Denver Indian Center, Inc.
Southern Ute Indian Tribe
Ute Mountain Ute Tribe

Delaware

Nanticoke Indian Association, Inc.

Florida

Florida Governor's Council on Indian Affairs
Miccosukee Corporation
Seminole Tribe of Florida

Hawaii

Alu Like, Inc.
State of Hawaii Dept. of Labor & Industrial Relations

Idaho

Nez Perce Tribe
Shoshone-Bannock Tribes

Indiana

Indiana American Indian Manpower Council

Kansas

Mid-American All Indian Center, Inc.
United Tribes of Kansas and Southeast Nebraska, Inc.

Louisiana

Inter-Tribal Council of Louisiana, Inc.

Maine

Tribal Governors, Inc.

Massachusetts

Mashpee-Wampanoag Indian Tribe Council, Inc.
North American Indian Center of Boston, Inc.

Michigan

Grand Traverse Band of Ottawa and Chippewa
Inter-Tribal Council of Michigan, Inc.
Michigan Indian Employment and Training Services, Inc.
North American Indian Association of Detroit, Inc.
The Pokagon Band of Potawatomi Indians
Sault Ste. Marie Tribe of Chippewa Indians
Southeastern Michigan Indians, Inc.

Minesota

American Indian Opportunities Industrialization Center
Bois Forte Reservation Tribal Council
Fond Du Lac Reservation Business Council
Leech Lake Reservation Tribal Council
Mille Lacs Band of Chippewa Indians
Minneapolis American Indian Center
Red Lake Tribal Council
White Earth Reservation Business Council

Mississippi

Mississippi Band of Choctaw

Missouri

American Indian Council, Inc.

Montana

Assiniboine & Sioux Tribes
Blackfeet Tribal Business Council
B.C. of the Chippewa Cree Tribe
Confederated Salish & Kootenai Tribes
Crow Tribe of Indians
Fort Belknap Indian Community
Northern Cheyenne Tribe

Nebraska

Indian Center, Inc.
Winnebago Tribe

Nevada

Inter-Tribal Council of Nevada, Inc.
Las Vegas Indian Center, Inc.
Shoshone-Paiute Tribes

New Jersey

Powhatan Renape Nation

New Mexico

Alamo Navajo School Board, Inc.
All Indian Pueblo Council, Inc.
Eight Northern Indian Pueblos Council
Mescalero Apache Tribe
National Indian Youth Council
Pueblo of Laguna
Pueblo of Zuni
Ramah Navajo School Board, Inc.
Santa Clara Indian Pueblo
Santo Domingo Tribe

New York

American Indian Community House, Inc.
Native American Cultural Center, Inc.
Native American Community Services of Erie & Niagara Counties
St. Regis Mohawk Tribe
Seneca Nation of Indians

North Carolina

Cumberland County Association for Indian People
Eastern Band of Cherokee Indians
Guilford Native American Association
Haliwa-Saponi Tribe, Inc.
Lumbee Regional Development Association, Inc.
Metrolina Native American Association
North Carolina Commission of Indian Affairs

North Dakota

Spirit Lake Sioux Tribe
Standing Rock Sioux Tribe
Three Affiliated Tribes
Turtle Mountain Band of Chippewa Indians
United Tribes Technical College

Ohio

North American Indian Cultural Center, Inc.

Oklahoma

Caddo Indian Tribe of Oklahoma
Cherokee Nation of Oklahoma
Cheyenne-Arapaho Tribes of Oklahoma
Chickasaw Nation
Choctaw Nation of Oklahoma
Citizen Potawatomi Nation
Comanche Indian Tribe
Creek Nation of Oklahoma
Four Tribes Consortium of Oklahoma
Inter-Tribal Council of N.E. Oklahoma
Kiowa Tribe of Oklahoma
Oklahoma Tribal Assistance Program, Inc.
Osage Nation
Pawnee Tribe of Oklahoma
Ponca Tribe of Oklahoma
Seminole Nation of Oklahoma
United Urban Indian Council, Inc.

Oregon

Confederated Tribes of Siletz Indians
Confederated Tribes of the Umatilla Indian Reservation
Confederated Tribes of Warm Springs
Organization of Forgotten Americans, Inc.

Pennsylvania

Council of Three Rivers

Rhode Island

Rhode Island Indian Council, Inc.

South Carolina

South Carolina Indian Development Council, Inc.

South Dakota

Cheyenne River Sioux Tribe
Lower Brule Sioux Tribe
Oglala Sioux Tribe
Rosebud Sioux Tribe
Sisseton-Wahpeton Sioux Tribe
United Sioux Tribes Development Corporation

Texas

Alabama-Coushatta Indian Tribal Council

Utah

Indian Center Employment Services, Inc.
Ute Indian Tribe

Vermont

Abenaki Self-Help Association/New Hampshire Indian Council

Virginia

Mattaponi-Pamunkey-Monacan Consortium

Washington

American Indian Community Center
Colville Confederated Tribes
Lummi Indian Business Council
Makah Tribal Council
Puyallup Tribe of Indians
Seattle Indian Center, Inc.
The Tulalip Tribes
Western Washington Indian Employment and Training Program

Wisconsin

Ho-Chunk Nation
Lac Courte Oreilles Tribal Governing Board
Lac Du Flambeau Band of Lake Superior Chippewas
Menominee Indian Tribe of Wisconsin
Milwaukee Area American Indian Manpower Council, Inc.
Oneida Tribe of Indians of Wisconsin
Wisconsin Indian Consortium

Wyoming

Shoshone & Arapahoe Tribes Joint Business Council

Note: Current JTPA section 401 grantees who do not appear on the above list were denied waivers either because their performance for Program Years 1996 and 1997 was not satisfactory or because they

have not been section 401 grantees for two full program years.

Signed at Washington, DC this 13th day of November, 1998.

Leroy Bingham,

Chief, Division of Indian and Native American Programs.

Anna W. Goddard,

Director, Office of National Programs.

E. Fred Tello,

Grant Officer, Office of Grants and Contracts Management, Division of Acquisition and Assistance.

[FR Doc. 98–31079 Filed 11–19–98; 8:45 am]

BILLING CODE 4510–30–P

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division; Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR Part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR Part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedes decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR Parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR Part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department. Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modifications to General Wage Determination Decisions

The number of decisions listed in the Government Printing Office document entitled ''General Wage Determinations Issued Under The Davis-Bacon And Related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volumn I

New York:
- NY980002 (FEB. 13, 1998)
- NY980003 (FEB. 13, 1998)
- NY980011 (FEB. 13, 1998)
- NY980013 (FEB. 13, 1998)
- NY980032 (FEB. 13, 1998)
- NY980034 (FEB. 13, 1998)
- NY980042 (FEB. 13, 1998)
- NY980044 (FEB. 13, 1998)
- NY980046 (FEB. 13, 1998)
- NY980047 (FEB. 13, 1998)

Volume II

Pennsylvania:
- PA980001 (FEB. 13, 1998)
- PA980004 (FEB. 13, 1998)
- PA980017 (FEB. 13, 1998)
- PA980033 (FEB. 13, 1998)
- PA980042 (FEB. 13, 1998)

Volume III

Florida:
- FL980009 (FEB. 13, 1998)
- FL980013 (FEB. 13, 1998)

Volume IV

Indiana:
- IN980001 (FEB. 13, 1998)
- IN980002 (FEB. 13, 1998)
- IN980003 (FEB. 13, 1998)
- IN980004 (FEB. 13, 1998)
- IN980005 (FEB. 13, 1998)
- IN980006 (FEB. 13, 1998)
- IN980016 (FEB. 13, 1998)
- IN980020 (FEB. 13, 1998)
- IN980059 (FEB. 13, 1998)

Michigan:
- MI980001 (FEB. 13, 1998)
- MI980002 (FEB. 13, 1998)
- MI980005 (FEB. 13, 1998)
- MI980012 (FEB. 13, 1998)
- MI980030 (FEB. 13, 1998)
- MI980031 (FEB. 13, 1998)
- MI980047 (FEB. 13, 1998)
- MI980060 (FEB. 13, 1998)
- MI980062 (FEB. 13, 1998)
- MI980070 (FEB. 13, 1998)
- MI980075 (FEB. 13, 1998)
- MI980080 (FEB. 13, 1998)
- MI980081 (FEB. 13, 1998)
- MI980082 (FEB. 13, 1998)
- MI980083 (FEB. 13, 1998)
- MI980084 (FEB. 13, 1998)

Volume V

Kansas:
- KS980004 (FEB. 13, 1998)
- KS980005 (FEB. 13, 1998)
- KS980007 (FEB. 13, 1998)
- KS980009 (FEB. 13, 1998)
- KS980013 (FEB. 13, 1998)
- KS980019 (FEB. 13, 1998)
- KS980021 (FEB. 13, 1998)
- KS980023 (FEB. 13, 1998)
- KS980025 (FEB. 13, 1998)
- KS980026 (FEB. 13, 1998)
- KS980067 (FEB. 13, 1998)

Oklahoma:
- OK980014 (FEB. 13, 1998)
- OK980016 (FEB. 13, 1998)
- OK980017 (FEB. 13, 1998)
- OK980028 (FEB. 13, 1998)
- OK980034 (FEB. 13, 1998)
- OK980035 (FEB. 13, 1998)
- OK980036 (FEB. 13, 1998)
- OK980037 (FEB. 13, 1998)
- OK980038 (FEB. 13, 1998)
- OK980043 (FEB. 13, 1998)

Texas:
- TX980003 (FEB. 13, 1998)
- TX980007 (FEB. 13, 1998)
- TX980033 (FEB. 13, 1998)
- TX980034 (FEB. 13, 1998)

TX980035 (FEB. 13, 1998)
TX980037 (FEB. 13, 1998)
TX980069 (FEB. 13, 1998)

Volume VI

Colorado:
CO980001 (FEB. 13, 1998)
CO980003 (FEB. 13, 1998)
CO980004 (FEB. 13, 1998)
CO980005 (FEB. 13, 1998)
CO980006 (FEB. 13, 1998)
CO980007 (FEB. 13, 1998)
CO980008 (FEB. 13, 1998)
CO980009 (FEB. 13, 1998)
CO980010 (FEB. 13, 1998)
CO980014 (FEB. 13, 1998)
CO980016 (FEB. 13, 1998)
CO980018 (FEB. 13, 1998)
CO980020 (FEB. 13, 1998)
CO980021 (FEB. 13, 1998)
CO980023 (FEB. 13, 1998)
CO980025 (FEB. 13, 1998)
North Dakota:
ND980002 (FEB. 13, 1998)
Oregon:
OR980001 (FEB. 13, 1998)
OR980017 (FEB. 13, 1998)
Washington:
WA980001 (FEB. 13, 1998)
WA980002 (FEB. 13, 1998)
WA980008 (FEB. 13, 1998)
WA980009 (FEB. 13, 1998)
Wyoming:
WY980008 (FEB. 13, 1998)

Volume VII

California:
CA980004 (FEB. 13, 1998)
CA980009 (FEB. 13, 1998)
CA980027 (FEB. 13, 1998)
CA980029 (FEB. 13, 1998)
CA980030 (FEB. 13, 1998)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related Acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under The Davis-Bacon and Related Acts.'' This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

The general wage determinations issued under the Davis-Bacon and related Acts are available electronically by subscription to the FedWorld Bulletin Board System of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402, (202) 512–1800. When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the seven separate volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates are distributed to subscribers.

Signed at Washington, D.C., this 12th day of November 1998.

Margaret J. Washington,

Acting Chief, Branch of Construction Wage Determinations.

[FR Doc. 98–30664 Filed 11–19–98; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Bureau of Labor Statistics

Labor Research Advisory Council; Notice of Meetings and Agenda

The Fall meetings of committees of the Labor Research Advisory Council will be held on December 8, 9, 10 and 17, 1998. All of the meetings for December 8, 9, and 10 will be held in the Conference Center of the Postal Square Building (PSB), 2 Massachusetts Ave., NE, Washington, DC. The December 17th meeting of the Committee on Occupational Safety and Health Statistics will be held in Conference Room 4328, in the Postal Square Building.

The Labor Research Advisory Council and its committees advise the Bureau of Labor Statistics with respect to technical matters associated with the Bureau's programs. Membership consists of union research directors and staff members. The schedule and agenda of the meetings are as follows:

Tuesday, December 8, 1998

1:30 p.m.—Committee on Compensation and Working Conditions—Meeting Room 9/10

1. Compensation inequality
2. Developing publication standards for the ECI
3. Davis Bacon benefits tests
4. Other business

Wednesday, December 9, 1998

9:30 a.m.—Committee on Employment and Unemployment Statistics—Meeting Room 9/10

1. Update on Office of Employment and Unemployment Statistics management staffing
2. Update on National Longitudinal Survey program
3. Overview of efforts to measure employment of persons with disabilities
4. Occupational Employment Statistics State and Area estimates for the 1997 survey and current research proposals for Davis-Bacon data collection
5. Report on the Workforce Investment Act

1:30 p.m.—Committee on Foreign Labor Statistics Meeting Room 9/10

1. BLS international cooperation activities
2. Recent developments in international labor markets

Committee on Productivity, Technology and Growth—Meeting Room 9/10

1. Plans for development and publication of 1998–2008 projections and other scheduled analyses and publications of the Office of Employment Projections
2. Recent developments in the Office of Productivity and Technology
3. Results from the expanded industry productivity database

Thursday, December 10, 1998

1:30 p.m. Committee on Prices and Living Conditions Meeting Room 9/10

1. Experimental Consumer Price Index for the elderly
2. Healthcare costs in the Consumer Price Index
3. Review of policy on expenditure weight updates in the Consumer Price Index
4. Other business

Thursday, December 17, 1998

10:00 a.m.–1:00 p.m.—Committee on Occupational Safety and Health Statistics—Conference Room 4328

1. Report on the 1997 Survey of Occupational Injuries and Illnesses
2. Report on the number and incidence of days away from work cases and the number and incidence of cases involving restricted activity only
3. Participation of additional States in the Survey of Occupational Injuries and Illnesses
4. Followback epidemiology studies
5. Report on the status of the Census of Fatal Occupational Injuries
6. Discussion of the report on traumatic occupational injury research needs and priorities prepared by the National Occupational Research Agenda Traumatic Injury Team

The meetings are open to the public. Persons planning to attend these meetings as observers may want to contact Wilhelmina Abner at (Area Code 202) 606–5970.

Signed at Washington, DC this 13th day of November 1998.

Katharine G. Abraham,

Commissioner.

[FR Doc. 98–31082 Filed 11–19–98; 8:45 am]

BILLING CODE 4510–24–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Occupational Safety and Health Administration, Labor.

ACTION: Notice.

SUMMARY: The Occupational Safety and Health Administration (OSHA) is announcing that a collection of information has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. This document announces the OMB approval number and expiration date.

FOR FURTHER INFORMATION CONTACT:

Cathy Oliver, Division of Voluntary Programs, Directorate of Federal-State Operations, Occupational Safety and Health Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20010, (202) 693–2213.

SUPPLEMENTARY INFORMATION: In 62 FR 52153 dated 10/6/1997, the Agency announced its intent to request approval from the OMB for certain information collection requirements contained in the Voluntary Protection Programs (VPP) application procedures. In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), OMB has approved the collection of this information and assigned OMB control number 1218–0239. The approval expires 7/31/2001. Under 5 CFR 1320.5(b), an Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

Dated: November 16, 1998.

Charles N. Jeffress,

Assistant Secretary.

[FR Doc. 98–31081 Filed 11–19–98; 8:45 am]

BILLING CODE 4510–26–M

NATIONAL COMMISSION ON LIBRARIES AND INFORMATION SCIENCE

SUNSHINE ACT MEETING

The U.S. National Commission on Libraries and Information Science (NCLIS) Sunshine Act Meeting

TIME, DATE, AND PLACE: NCLIS Business Meeting, December 3 and 4, 1998, 9:00 a.m.–5:00 p.m. and 9:00 a.m.–3:00 p.m., respectively, Seattle Public Library, 100 Fourth Avenue, Seattle, WA.

DISCUSSION TOPICS:

Discussion and recommendations regarding NCLIS Open Hearing, ''Kids and the Internet: the Promise and the Perils,'' held November 10, 1998
Briefing, Washington State Library Commission
Briefing, Gates Library Foundation
Update and reports on NCLIS committee, programs, and projects
Administrative matters

To request further information or to make special arrangements for physically challenged persons, contact Barbara Whiteleather (202–606–9200) no later than one week in advance of the meeting.

Dated: November 17, 1998.

Robert S. Willard,

NCLIS Executive Director.

[FR Doc. 98–31189 Filed 11–18–98; 11:00 am]

BILLING CODE 7527–$$–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Combined Arts Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Combined Arts Panel, Museum/Visual Arts/Design Section (Education & Access category) to the National Council on the Arts will be held on December 8–11, 1998. The panel will meet from 9:00 a.m. to 6:00 p.m. on December 8–10, and from 9:00 a.m. to 5:00 p.m. on December 11, in Room 716 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506. A portion of this meeting, from 12:30 p.m. to 2:00 p.m. on December 11, will be open to the public for a policy discussion.

The remaining portions of this meeting, meet from 9:00 a.m. to 6:00 p.m. on December 8–10, and from 9:00 a.m. to 12:30 p.m. and 2:30 p.m. to 5:00 p.m. on December 11, are for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 14, 1998, these sessions will be closed to the public pursuant to (c)(4)(6) and (9)(B) of section 552b of Title 5, United States Code.

Any person may observe meetings, or portions thereof, of advisory panels which are open to the public, and, if time allows, may be permitted to participate in the panel's discussions at the discretion of the panel chairman and with the approval of the full-time Federal employee in attendance.

If you need special accommodations due to a disability, please contact the Office of AccessAbility, National Endowment for the Arts, 1100 Pennsylvania Avenue, NW., Washington, DC 20506, 202/682–5532, TDY–TDD 202/682–5496, at least seven (7) days prior to the meeting.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506, or call 202/682–5691.

Dated: November 16, 1998.

Kathy Plowitz-Worden,

Panel Coordinator, Panel Operations, National Endowment for the Arts.

[FR Doc. 98–31086 Filed 11–19–98; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Partnership Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of Partnership Panel, Regional Section A, (Regional Partnership Agreements category) to the National Council on the Arts will be held on December 11, 1998. The panel will meet in teleconference from 3:00 p.m. to 5:00 p.m. in Room 726 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW., Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the

determination of the Chairman of May 14, 1998, these sessions will be closed to the public pursuant to subsection (c)(4), (6), and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Panel Coordinator, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5691.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 98–31087 Filed 11–19–98; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts; Partnership Advisory Panel

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), as amended, notice is hereby given that a meeting of the Partnership Panel, Regional Section B, (Regional Partnership Agreements category) to the National Council on the Arts will be held on December 15, 1998. The panel will meet in teleconference from 3:00 p.m. to 5:00 p.m. in Room 726 at the Nancy Hanks Center, 1100 Pennsylvania Avenue, NW, Washington, DC 20506.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman of May 14, 1998, these sessions will be closed to the public pursuant to subsection (c)(4), (6) and (9)(B) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Ms. Kathy Plowitz-Worden, Panel Coordinator, National Endowment for the Arts, Washington, DC 20506, or call (202) 682–5691.

Dated: November 16, 1998.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 98–31088 Filed 11–19–98; 8:45 am]

BILLING CODE 7537–01–M

NATIONAL SCIENCE FOUNDATION

Notice of Permit Applications Received Under the Antarctic Conservation Act of 1978 (Pub. L. 95–541)

AGENCY: National Science Foundation.

ACTION: Notice of Permit Applications Received under the Antarctic Conservation Act of 1978, Public Law 95–541.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permit applications received to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act at title 45 part 670 of the Code of Federal Regulations. This is the required notice of permit applications received.

DATES: Interested parties are invited to submit written data, comments, or views with respect to these permit applications by December 19, 1998. Permit applications may be inspected by interested parties at the Permit Office, address below.

ADDRESSES: Comments should be addressed to Permit Office, Room 755, Office of Polar Programs, National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230.

FOR FURTHER INFORMATION CONTACT: Nadene G. Kennedy at the above address or (703) 306–1030.

SUPPLEMENTARY INFORMATION: The National Science Foundation, as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541), has developed regulations that implement the ''Agreed Measures for the Conservation of Antarctic Fauna and Flora'' for all United States citizens. The Agreed Measures, developed by the Antarctic Treaty Consultative Parties, recommended establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas requiring special protection. The regulations establish such a permit system to designate Special Protected Areas and Sites of Special Scientific Interest.

The applications received are as follows:

Permit Application No. 99–011

1. *Applicant:* Erland A. K. Fogelberg, Vice President, Orient Lines, 1510 S.E. 17th Street, Suite 400, Fort Lauderdale, Florida 33316.

Activity for Which Permit is Requested: Enter Antarctic Specially Protected Areas. The applicant proposes to conduct educational visits, for passengers and staff members of the R/V Marco Polo, to the following Ross Island areas: Hut and associated artifacts, Backdoor Bay, Cape Royds (ASPA #156), and Cape Evans Historic Site (ASPA #154), and Discovery Hut, Hut Point (ASPA #157). All visits will be conducted in accordance with the relevant Management Plans for each site.

Location: ASPA #154—Cape Evans, Ross Island, ASPA #156—Cape Royds, Ross Island, and ASPA #157—Hut Point, Ross Island.

Dates: February 1, 1999—February 28, 2004.

Permit Application No. 99–014

2. *Applicant:* Bruce Rheins, CBS News, 7800 Beverly Boulevard, Los Angeles, California 90036, Fort Lauderdale, Florida 33316.

Activity for Which Permits is Requested: Enter Antarctic Specially Protected Areas. The applicant proposes to enter Antarctic Specially Protected Areas to film scientific projects in the field for educational purposes. Access to these sites will be on an opportunistic basis and the film team will be under constant supervision and direction.

Location:

ASPA #105—Beaufort Island, Ross Sea
ASPA #106—Cape Hallett, Victoria Land
ASPA #116—''New College Valley'', Caughley Beach, Cape Bird
ASPA #118—Cryptogram Ridge, Mount Melbourne
ASPA #119—Forlidas Pond & Davis Valley Ponds
ASPA #121—Cape Royds, Ross Island
ASPA #122—Arrival Heights, Hut Point Peninsula
ASPA #123—Barwick Valley, Victoria Land
ASPA #124—Cape Crozier, Ross Island
ASPA #130—Tramway Ridge, Mt. Erebus
ASPA #131—Canada Glacier, Lake Fryxell, Taylor Valley
ASPA #137—Northwest White Island, McMurdo Sound
ASPA #138—Linneaus Terrace, Asgard Range

Dates: January 5, 1999–January 24, 1999.

Permit Application No. 99–015

3. *Applicant:* Ronald G. Koger, Project Director, Antarctic Support Associates, 61 Inverness Drive East, Suite 300, Englewood, Colorado 80112.

Activity for Which Permit Requested: Enter Antarctic Specially Protected Area. The applicant proposes to enter the U.S. Research Station, ''Copacabana'', located within ASPA #128, Western Shore of Admiralty Bay, King George Island. Access to the sites

is for purposes of moving research personnel and supplies from the ship to shore via zodiac, tasks associated with station opening and closing, and maintenance and servicing of station facilities and equipment. Landings at the site will be conducted via zodiac, with personnel transiting from the shoreline to the hut on foot.

Location: ASPA #128—Western Shore of Admiralty Bay, King George Island.

Dates: January 1, 1999–April 1, 2000.

Permit Application No. 99–016

4. *Applicant:* Donal T. Manahan, Department of Biological Sciences, University of Southern California, Los Angeles, California 90089–0371.

Activity for Which Permit is Requested: Introduction of a Non-indigenous Species into Antarctica. The applicant proposes to introduce cultures of *E. coli* which are a component of several molecular biology DNA cloning kits that will be used in a course in Integrative Biology and Adaptation of Antarctic Marine Organisms. *E. coli* will be used to replicate DNA during gene cloning and the bacterial stocks will be transported, with other kit reagents, frozen on dry ice (−80°). All experiments will be conducted in the Crary laboratory facilities at McMurdo Station.

Immediately after an experiment, using *E. coli* cultures, all media and materials coming into contact with the bacteria will be sterilized by autoclaving. Standard P–2 containment guidelines will be followed for the subsequent disposal of all materials and supplies. All *E. coli* cultures will be sterilized and killed at the end of the project.

Location: Crary Science and Engineering Laboratory, McMurdo Station, Antarctica Island.

Dates: December 29, 1998–February 15, 1999.

Nadene G. Kennedy,

Permit Officer, Office of Polar Programs.

[FR Doc. 98–30995 Filed 11–19–98; 8:45 am]

BILLING CODE 7555–01–M

NATIONAL SKILL STANDARDS BOARD

Notice of Open Meeting

AGENCY: National Skill Standards Board.

ACTION: Notice of open meeting.

SUMMARY: The National Skill Standards Board was established by an Act of Congress, the National Skill Standards Act, Title V, Pub. L. 103–227. The 27-member National Skill Standards Board serves as a catalyst for the development and implementation of a national system of voluntary skill standards and certification through voluntary partnerships. These partnerships will have the full and balanced participation of business, industry, labor, education and other key groups.

TIME AND PLACE: The meeting will be held from 8:30 a.m to approximately 12:30 p.m. on Friday, December 11, in the Hotel Washington located at 515 15th Street, NW, Washington, DC.

AGENDA: The agenda for the Board Meeting will include: an update on the Board's Strategic Plan; reports from the Board's committees; presentations from the Voluntary Partnerships—Manufacturing, Installation and Repair (Manufacturing Skill Standards Council) and Retail Trade, Wholesale Trade, Real Estate & Personal Services (Sales and Services); and reports from Convening Groups representing the following industry clusters: Business & Administrative Services; Construction; Education and Training; Finance & Training; Restaurants, Lodging, Hospitality & Tourism, and Amusement & Recreation; and Telecommunications, Computers, Arts & Entertainment, and Information.

PUBLIC PARTICIPATION: The meeting is open to the public. Seating is limited and will be available on a first-come, first-served basis. (Seats will be reserved for the media.) If special accommodations are needed contact Michele Russo at (202) 254–8628 extension 10.

FOR FURTHER INFORMATION CONTACT: Tracy Marshall, Director of Operations at (202) 254–8628 extension 13.

Signed in Washington, DC, this 13th day of November 1998.

Edie West,

Executive Director, National Skill Standards Board.

[FR Doc. 98–31080 Filed 11–19–98; 8:45 am]

BILLING CODE 4510–23–M

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–269, 50–270, and 50–287]

Duke Energy Corporation (Oconee Nuclear Station, Units 1, 2, and 3); Exemption

I

The Duke Energy Corporation (Duke/the licensee) is the holder of Facility Operating License Nos. DPR–38, DPR–47, and DPR–55, that authorize operation of the Oconee Nuclear Station, Units 1, 2, and 3 (Oconee), respectively. The licenses provide, among other things, that the facilities are subject to all rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (the Commission) now or hereafter in effect.

The facilities consist of pressurized water reactors located on Duke's Oconee site in Seneca, Oconee County, South Carolina.

II

Title 10 of the Code of Federal Regulations (10 CFR) Part 50, § 50.46(a)(1)(i), requires that each pressurized light-water nuclear power reactor must be provided with an emergency core cooling system (ECCS) that is designed so that its calculated cooling performance following postulated loss-of-coolant accidents conforms to the criteria set forth in paragraph 50.46(b). ECCS cooling performance must be calculated in accordance with an acceptable evaluation model and must be calculated for a number of postulated loss-of-coolant accidents (LOCAs) of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated small and large break LOCAs are calculated that will ensure adequate long-term cooling.

By letter dated September 17, 1998, the licensee described a modification that would add voltage and frequency protection for the Oconee loads when they are supplied from a Keowee hydro unit. The protection would separate Oconee loads from a Keowee unit if that unit's voltage or frequency becomes greater than 110 percent or less than 90 percent of rated value at any time after loading. The planned design would also delay energizing the Oconee loads on the underground power path until the Keowee unit reaches greater than 90 percent voltage and frequency. The existing design allows early loading of the underground path Keowee unit at approximately 60 percent voltage. During the design phase of this modification, while considering the frequency overshoot that the Keowee units normally experience during an emergency start, questions arose concerning whether the emergency power system should be loaded at 60 percent or 90 percent. To provide needed data to resolve this question, the Keowee Emergency Power and Engineered Safeguards Functional (KEP/ESF) Test is planned.

The test is scheduled during the Unit 3 outage, will be performed on the Keowee underground path, and will consist of two parts. One part will load the Keowee unit at its present design of approximately 60 percent rated voltage

and frequency. The second part will use the same loads, but the Keowee unit will be loaded at approximately 90 percent rated voltage and frequency. Test data will be collected throughout the Oconee emergency power system (EPS) during the test. The licensee will then review this data to determine which delayed loading modifications should be implemented.

In the September 17, 1998, letter, Duke explained it has determined that this test involves an unreviewed safety question, which, therefore, requires NRC approval prior to performing the test. This request is being processed separately. The licensee also indicated that in the extremely unlikely (probability, according to the licensee, of 2 E–9) event that a real LOCA with loss of offsite power (LOOP) were to occur on either of the Oconee operating units (Unit 1 or 2) simultaneously when the test is initiated on Unit 3, the Oconee EPS would be placed in a condition outside the design basis. The EPS may not be capable of handling the electrical loading of two instantaneous LOCA/LOOP events without some safety related equipment being adversely affected. However, the EPS would be able to handle the electrical loading if the two events are offset in time by approximately 10 seconds to allow the first unit's load to reach a steady-state condition prior to starting of the second unit's emergency loads. Therefore, this 10-second window of vulnerability causes an infinitesimally small, but non-zero, increase in the probability of a malfunction of equipment important to safety and increases the potential consequences of a LOCA/LOOP event during the performance of the test.

The ECCS is designed to assure that the consequences of the spectrum of LOCA accidents, coincident with a LOOP, are within the performance criteria specified in 10 CFR 50.46(b). As explained in the licensee's letter dated October 21, 1998, the planned test on Unit 3 could challenge this criteria in the extremely unlikely event that a LOCA and LOOP on Units 1 or 2 occurred coincident with the start of the test on Unit 3. Therefore, in the October 21 letter and pursuant to 10 CFR 50.12, the licensee applied for an exemption from 10 CFR 50.46.

III

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR Part 50, when (1) the exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. The requested exemption meets the special circumstances of 10 CFR 50.12(a)(2)(iv) in that the exemption would result in benefit to the public health and safety that compensates for the small decrease in safety that may result from granting the exemption. The benefit is that this test will produce data to support a decision on implementation of proposed modifications to the loading methodology of the Keowee hydro unit to improve the overall reliability of the Oconee EPS, which supports the ECCS. The test is being conducted under a comprehensive test plan that includes special management oversight, ''just in time training'' for the operators, including power system failures, and detailed contingency plans. Other precautions to protect the power systems will be in place, which are described in more detail in the licensee's September 17, 1998, submittal. No other work will be allowed on the EPS of any unit during this test. A Lee gas turbine will be powering CT–5 to provide additional defense in depth for the EPS during the test. This minimizes the likelihood of a plant-centered LOOP occurring during the test period. Additionally, precautions have been taken so that the planned LOOP tests on Unit 3 will not propagate to the operating units. Therefore, the likelihood of two LOCA/LOOP events occurring within approximately 10 seconds of each other (one event being the LOCA/LOOP test on Unit 3 and the second event being an actual LOCA/LOOP on Unit 1 or 2) is low during the postulated period of 24-hour duration of the KEP/ESF Test.

IV

For the foregoing reasons, the NRC staff has concluded that the licensee's proposed exemption request from the requirements of 10 CFR 50.46(b) for the KEP/ESF Test is justified. The probability of a coincident LOCA/LOOP on one of the operating units (approximately 2E–9, as estimated by the licensee) was calculated for the entire duration (24 hours) of the KEP/ESF Test. If a separation in time of greater than 10 seconds exists between initiation of the test and a coincident event, the ECCS on the affected unit will be capable of performing its intended safety function. The benefit to the Oconee Emergency Power System from performing this test, along with the low probability of a concurrent LOCA/LOOP on one of the two operating Oconee units, provides justification for granting this exemption request. In addition, granting of the exemption to allow performance of the test will not present an undue risk to public health and safety and is consistent with the common defense and security. The NRC staff has determined that there are special circumstances present, as specified in 10 CFR 50.12(a)(2)(iv), in that the exemption will result in a benefit to the public health and safety that compensates for the decrease in safety that may result from the granting the exemption because the exemption will allow the test to be performed that will produce data to support an implementation decision for a proposed modification that will improve the overall reliability of the Oconee emergency power system.

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12(a), the exemption is authorized by law, will not endanger life or property or common defense and security, and is, otherwise, in the public interest. Therefore, the Commission hereby grants Duke an exemption from the requirements of 10 CFR 50.46(b) for Units 1, 2, and 3 during the 24-hour period when the tests are being conducted on Unit 3 as requested in the submittal.

Pursuant to 10 CFR 51.32, the Commission has determined that the granting of this exemption will not result in any significant effect on the quality of the human environment (63 FR 63754).

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 16th day of November 1998.

For the Nuclear Regulatory Commission.

Samuel J. Collins,

Director, Office of Nuclear Reactor Regulation.

[FR Doc. 98–31025 Filed 11–19–98; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 55–32443–SP; ASLBP No. 99–755–01–SP]

Atomic Safety and Licensing Board; Michel A. Philippon, (Denial of Senior Operator License Application); Notice of Hearing and of Opportunity To Petition for Leave To Intervene or To Participate as an Interested Governmental Entity

November 16, 1998.

Before Administrative Judges: Thomas S. Moore, Presiding Officer, Dr. Charles N. Kelber, Special Assistant.

On October 4, 1998, the NRC staff issued a notice of denial of application for a senior reactor operator's (SRO) license to Michel A. Philippon. In that letter, the staff advised Mr. Philippon that although he had passed the written portion of the SRO examination administered to him on April 6, 1998, his application was being denied because he failed to pass the operating test portion of the examination.

On October 16, 1998, Mr. Philippon filed a timely hearing request challenging the staff's denial of his SRO license application. On October 26, 1998, the Commission referred Mr. Philippon's hearing request to the Atomic Safety and Licensing Board Panel for the appointment of a presiding officer to conduct any necessary proceedings. On October 28, 1998, the Chief Administrative Judge of the Panel appointed Administrative Judge Thomas S. Moore, to act as the Presiding Officer, and Administrative Judge Charles N. Kelber, to serve as Special Assistant to the Presiding Officer.

After receiving the staff's November 6, 1998 answer to Mr. Philippon hearing request, on November 13, 1998, the Presiding Officer issued an order granting Mr. Philippon's hearing request.

Please take notice that a hearing will be conducted in this proceeding. This hearing will be governed by the informal hearing procedures set forth in 10 CFR Part 2, Subpart L (10 CFR 2.1201–.1263).

Further, in accordance with 10 CFR 2.1205(j), please take notice that within thirty (30) days from the date of publication of this notice of hearing in the **Federal Register** (1) any person whose interest may be affected by this proceeding may file a petition for leave to intervene; and (2) any interested governmental entity may file a request to participate in this proceeding in accordance with 10 CFR 2.1211(b). Any petition for leave to intervene must set forth the information required by 10 CFR 2.1205(e), including a detailed description of (1) the interest of the petitioner in the proceeding; (2) how that interest may be affected by the results of the proceeding, including the reasons why the petitioner should be permitted to intervene with respect to the factors set forth in 10 CFR 2.1205(h); (3) the petitioner's areas of concern regarding the staff's October 4, 1998 denial of Mr. Philippon's SRO license application; and (4) the circumstances establishing that the petition to intervene is timely in accordance with 10 CFR 2.1205(d). In accordance with 10 CFR 2.1211(b), any request to participate by an interested governmental entity must state with reasonable specificity the requestor's areas of concern regarding the staff's October 4, 1998 denial of Mr. Philippon's SRO license application.

In addition, pursuant to 10 CFR 2.1211(a), any person not a party to the proceeding may submit a written limited appearance statement setting forth his or her position on the issues in this proceeding. These statements do not constitute evidence, but may assist the Presiding Officer and/or parties in defining the issues being considered. Persons wishing to submit a written limited appearance statement should send it to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. A copy of the statement also should be served on the Presiding Officer and the Special Assistant.

In the November 13, 1998 order, the Presiding Officer directed that on or before December 14, 1998, the staff shall file the hearing file for this proceeding. Once the hearing file is received, pursuant to 10 CFR 2.1233 the Presiding Officer will establish a schedule for the filing of written presentations by Mr. Philippon and the staff, which may be subject to supplementation to accommodate the grant of any intervention petition or request to participate by an interested governmental entity. After receiving the parties' written presentations, pursuant to 10 CFR 2.1233(a) and 2.1235, the Presiding Officer may submit written questions to the parties or any interested governmental entity or provide an opportunity for oral presentations by any party or interested governmental entity, which may include oral questioning of witnesses by the Presiding Officer.

Documents relating to this proceeding are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC.

Dated: November 16, 1998.

Thomas S. Moore,

Administrative Judge.

[FR Doc. 98–31023 Filed 11–19–98; 8:45 am]

BILLING CODE 7590–01–P

RAILROAD RETIREMENT BOARD

Agency Forms Submitted for OMB Review

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Railroad Retirement Board (RRB) has submitted the following proposal(s) for the collection of information to the Office of Management and Budget for review and approval.

Summary of Proposal(s)

(1) *Collection title:* Supplemental Information on Accident and Insurance.

(2) *Form(s) submitted:* SI–1c, SI–5, ID–3s, ID–3s–1, ID–3u, ID–30k, ID–30k–1.

(3) *OMB Number:* 3220–0036.

(4) *Expiration date of current OMB clearance:* 12/31/1998.

(5) *Type of request:* Revision of a currently approved collection.

(6) *Respondents:* Individuals or households, business or other for profit.

(7) *Estimated annual number of respondents:* 30,700.

(8) *Total annual responses:* 30,700.

(9) *Total annual reporting hours:* 1,875.

(10) *Collection description:* The Railroad Unemployment Insurance Act provides for the recovery of sickness benefits paid if an employee receives a settlement for the same injury for which benefits were paid. The collection obtains information about the person or company responsible for such payments that is needed to determine the amount of the RRB's entitlement.

ADDITIONAL INFORMATION OR COMMENTS: Copies of the form and supporting documents can be obtained from Chuck Mierzwa, the agency clearance officer (312–751–3363). Comments regarding the information collection should be addressed to Ronald J. Hodapp, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 and the OMB reviewer, Laura Oliven (202–395–7316), Office of Management and Budget, Room 10230, New Executive Office Building, Washington, DC 20503.

Chuck Mierzwa,

Clearance Officer.

[FR Doc. 98–31084 Filed 11–19–98; 8:45 am]

BILLING CODE 7905–01–M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 35–26941]

Filings Under the Public Utility Holding Company Act of 1935, as Amended (''Act'')

November 13, 1998.

Notice is hereby given that the following filing(s) has/have been made with the Commission pursuant to provisions of the Act and rules promulgated under the Act. All interested persons are referred to the application(s) and/or declaration(s) for

complete statements of the proposed transactions(s) and any amendment is/are available for public inspection through the Commission's Office of Public Reference.

Interested persons wishing to comment or request a hearing on the application(s) and/or declaration(s) should submit their views in writing by December 8, 1998, to the Secretary, Securities and Exchange Commission, Washington, DC 20549, and serve a copy on the relevant applicant(s) and/or declarants(s) at the address(es) specified below. Proof of service (by affidavit or, in case of an attorney at law, by certificate) should be filed with the request. Any request for hearing should identify specifically the issues of fact or law that are disputed. A person who so requests will be notified of any hearing, if ordered, and will receive a copy of any notice or order issued in the matter. After December 8, 1998, the application(s) and/or declaration(s), as filed or as amended, may be granted and/or permitted to become effective.

UtiliCorp United Inc. (70–9363)

UtiliCorp United Inc. (''UtiliCorp''), 20 West Ninth Street, Kansas City, Missouri 64105, a public utility holding company claiming exemption from registration under rule 10 of the Act, has filed an application under section 3(b) and rules 10 and 11 under the Act.

UtiliCorp is a publicly traded corporation which engages, through divisions, primarily in the sale and distribution of gas and electricity to retail and wholesale customers in several states, Canada, New Zealand and Australia. One of UtiliCorp's subsidiaries is Power New Zealand Limited (''PNZ''), which is also a foreign utility company exempt under section 33 of the Act.

UtiliCorp now requests an order under section 3(b) of the Act, exempting PNZ from all provisions of the Act, except section 9(a)(2). UtiliCorp states that PNZ will not derive any material part of its income, directly or indirectly, from sources within the United States. In addition, UtiliCorp states that PNZ is not, and does not own any securities of any company which is, a public utility or holding company operating in the United States.

UtiliCorp states that its investment in PNZ will not in any way diminish the ability of various state commissions that regulate the retail electric and gas operations of UtiliCorp to protect the interests of consumers in their respective states. UtiliCorp states that its domestic operations are, and will continue to be, fully separated from its foreign operations. UtiliCorp represents that it will maintain separate books of account for any of its subsidiaries that may control any foreign company. UtiliCorp further represents that it will provide access to these books and records to each state commission with rate jurisdiction to the extent not already required by law.

UtiliCorp states that, if an unqualified exemption under section 3(b) is granted, it intends to rely on rule 10 to provide it and intermediated parent to PNZ an exemption from the Act as holding companies due to their interests in PNZ. In addition, UtiliCorp asserts that it will rely on rule 11(b)(1) to provide an exemption from the approval requirements of sections 9(a)(2) and 10 to which UtiliCorp would otherwise be subject.

The Peoples Natural Gas Company, et al. (70–9379)

The Peoples Natural Gas Company (''PNG''), a gas public utility subsidiary company of Consolidated Natural Gas Company (''CNG''), a registered holding company, and CNG Producing Company (''CNGP''), a gas and oil exploration and production subsidiary company of CNG, both located at 625 Liberty Avenue, Pittsburgh, Pennsylvania 15222–3197 have filed an application-declaration under sections 9(a), 10 and 12(f) of the Act and rules 43 and 54 under the Act.

PNG has signed a binding letter of intent, contingent upon Commission approval, to sell all of its gas production properties (''Properties'') to CNGP. The Properties consist of PNG's interest in wells having reserves of approximately 41.9 billion cubic feet, together with associated oil and gas leases covering approximately 175,000 acres, related agreements and equipment, and certain portions of gathering lines.

The sale price for the Properties is approximately $14.5 million. This price represents the net book value of all the production properties as shown on PNG's books of account as of November 30, 1997, and will be adjusted for further depreciation at the time of closing.

Conectiv, et al. (70–9069)

Conectiv, a registered holding company, and its marketing subsidiary, Conectiv Energy Supply, Inc. (''CES''), both located at 800 King Street, Wilmington, DE 19899, Delmarva Capital Investments, Inc. (''DCI''), a nonutility subsidiary of Conectiv, Conectiv Services, Inc. (''CSI''), an energy-related company, both located at 252 Chapman Road, P.O. Box 6066, Newark, DE 19714, ATE Investment, Inc. (''ATE''), Atlantic Generation, Inc. (''AGI''), and Atlantic Southern Properties, Inc. (''ASP''), all nonutility subsidiaries of Conectiv, located at 5100 Harding Highway, Mays Landing, NJ 08330 have filed an application-declaration under sections 6(a), 7, 9(a), 10, 12(b), 12(c) and 12(f) of the Act and rules 45, 46 and 54 under the Act.

By order dated February 25, 1998 (HCAR No. 26832) (''Merger Order''), the Commission authorized Conectiv to consummate certain transactions (''Merger'') resulting in the acquisition by Conectiv of all of the outstanding voting securities of Delmarva Power & Light Company, an electric public utility company (''Delmarva''), and Atlantic City Electric Company, an electric public utility company (''ACE'').[1] Also as a result of the Merger and certain restructuring that was implemented contemporaneously with the Merger, Conectiv became the direct or indirect owner of various nonutility businesses.

Conectiv now proposes, through December 31, 2001, to simplify and consolidate its nonutility subsidiaries. The restructuring will be accomplished in two phases (''Phase One'' and ''Phase Two''). During Phase One, which will be implemented as soon as practicable following the issuance of an order by the Commission in this filing, the number of active direct nonutility subsidiaries of Conectiv will be reduced to six: (1) CSI, which will focus on energy-related services and the marketing of energy to retail customers; (2) CES, which will focus on energy supply and marketing to wholesale and industrial customers, including associates; (3) DCI, which will be renamed Conectiv Properties and Investments, Inc. (''CPI'') and will own the nonutility investments which are more passive in nature; (4) ASP, which will be merged into CPI in Phase Two; (5) AGI, which will be merged into CES in Phase Two; and (6) ATE, which will also be merged into CPI in Phase Two.

Phase One

To implement Phase One and reduce the number of direct non-utility subsidiaries, numerous actions must be effected, including the following proposed actions. Atlantic Energy Enterprises, Inc. (''AEE''), a direct nonutility subsidiary of Conectiv, that was formed as a holding company for Conectiv's nonutility investments, will

[1] Conectiv's two public utility subsidiaries (Delmarva and ACE) and their subsidiaries are unaffected by the proposed restructuring. Similarly, the system's service company, Conectiv Resource Partners, Inc., is unaffected.

be merged with and into Conectiv.[2] This action will make all seven wholly owned direct subsidiaries of AEE [3] direct holdings of Conectiv, for an interim period.

The applicants state that the factors that warranted the formation of special purpose subsidiaries for investment in various cogeneration projects no longer exist. Therefore, during Phase One, Pedrick General, Inc., Vineland General, Inc. and Binghamton General, Inc. (''collectively, ''General Partners''), all special purpose subsidiaries formed to act as general partners in Pedrick Cogeneration Limited, Inc., Vineland Cogneration Limited, Inc. and Binghamton Cogeneration Limited, (collectively, ''Cogen LLCs''), respectively. During Phase One, the General Partners, through a Short-form Merger, will be merged into their parent company, AGI, and the interest in the Cogen LLCs will be acquired by ATE.

During Phase One, CSI will be the surviving corporation following Short-form Mergers with Conectiv Solutions LLC, Altemp Energy Systems, Inc. and Power Consulting Group, Inc. Each of these companies has been authorized to provide energy-related services to retail consumers.[4] CSI will succeed to each of the authorities previously granted by the Commission to the predecessor companies in the Merger Order. CSI will also own four additional wholly owned subsidiaries: Conectiv Plumbing LLC, a company required under New Jersey law in connection with the heating, ventilation and air conditioning services provided by CSI; CTS; Conectiv Communications, Inc., an exempt telecommunications company; and Enerval.

During Phase One, CPI will become the holder of certain nonregulated investments that are passive in nature. However, for maximum flexibility, Conectiv requests authorization to retain certain passive investments if retention by Conectiv is deemed more appropriate for tax or other reasons. CPI will be the surviving corporation following Short-form Mergers with Delmarva Services Company, a corporation formed to own and finance an office building that is leased to Delmarva and its associates, Christiana Capital Management, Inc., a corporation that owns an office building leased to Delmarva, Atlantic Energy International, Inc., a corporation formed to broker used utility equipment to foreign countries and AET, a corporation formed to research and develop energy technology.

During Phase One, CES will be the surviving corporation following the Short-form Merger with Petron Oil Corporation, an energy marketing company. CES will also acquire the capital stock of Delmarva Operating Services Company (''DOSC''), a company providing management services to independent production companies or exempt wholesale generators. The capital stock in DOSC will be transferred up to Conectiv by capital dividend and then contributed by Conectiv to CES in an exempt capital contribution. Depending on the results of a pending tax analysis, the transfer may be accomplished by (1) an asset for stock merger in which Delmarva Capital Investments, Inc. (''DCI''), owner of the DOSC securities would receive CES securities in exchange for the assets or securities of DOSC, or (2) a dividend by DCI to Conectiv of the shares of DOSC followed by a capital contribution of the shares to CES.

Phase Two

Phase Two will be completed as appropriate giving consideration to: (1) Electric deregulation at the state and federal level; (2) tax implications; and (3) other related issues. Upon completion of Phase Two, the number of active direct nonutility subsidiaries of Conectiv (''Direct Nonutilities'') will be reduced from six to three (CSI, CES and CPI).

During Phase Two: (1) CSI will continue to focus on energy-related services and the marketing of energy to retail customers; (2) CES will continue to focus on energy supply and marketing to wholesale and industrial customers, and acquire AGI by Short-form Merger; and (3) CPI will continue to own certain nonutility investments which are more passive in nature, and acquire ASP and ATE by Short-form Mergers.

For the Commission, by the Division of Investment Management, under delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 98–31037 Filed 11–19–98; 8:45 am]

BILLING CODE 8010–01–M

[2] This merger will be a statutory short form merger (''Short-form Merger''). A Short-form Merger occurs when a parent corporation acquires all of the capital stock of a first tier subsidiary.

[3] AEE's direct subsidiaries are: ATE; AGI; Conectiv Thermal Systems, Inc. (''CTS'') (formerly Atlantic Thermal Systems, Inc.), a company that provides thermal energy management services; CoastalComm, Inc. (''Coastal''); Atlantic Southern Properties, Inc. (''ASP''); Atlantic Energy Technology, Inc. (''AET'') and Enerval, LLC (''Enerval''), a limited liability company that provides energy management services. CSI will acquire Enerval and CTS during Phase One.

Four of the six subsidiaries of CTS (Atlantic Jersey Thermal Systems, Inc., Atlantic Pacific Las Vegas LLC, Atlantic-Pacific Glendale LLC and Thermal Energy L.P.I) will be unaffected by the restructuring. Atlantic Paxton Cogeneration, Inc. has been dissolved and ATS Operating Services, Inc. may be merged with Thermal Energy L.P.I in Phase Two.

[4] *See Conectiv,* Holding Company Act Release No. 26832 (Feb. 25, 1998).

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application to Withdraw From Listing and Registration; (Redwood Empire Bancorp, Common Stock, No Par Value) File No. 1–10868

November 16, 1998.

Redwood Empire Bancorp (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified security (''Security'') from listing and registration on the American Stock Exchange, Inc. (''Amex'' or ''Exchange'').

The reasons cited in the application for withdrawing the Security from listing and registration include the following:

The Company's Board of Directors approved a plan to switch from listing the Security on Amex to listing the Security on Nasdaq in order to provide the Company with greater visibility and the Company's stockholders with greater liquidity. The Company notified Amex of its intent to withdraw its Security from listing and registration on the Exchange and to apply to Nasdaq.

The Security has begun trading on the Nasdaq and the Company believes it is no longer necessary to continue trading on the Amex.

The Company has complied with Rule 18 of Amex by filing with the Exchange a certified copy of the resolution adopted by the Board of Directors authorizing the withdrawal of the Security and by providing Amex with the reasons for the proposed withdrawal.

The Exchange has informed the Company that Amex will not object to the Company's application to withdrawal its Security from listing and registration on the Exchange. This application relates solely to the withdrawal from listing of the Company's Security from the Amex.

By reason of Section 12 of the Act and the rules and regulations of the Commission thereunder, the Company shall continue to be obligated to file

reports under the Act with the Commission.

Any interested person may, on or before December 8, 1998, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 98–31036 Filed 11–19–98; 8:45 am]

BILLING CODE 8010–01–M

SECURITIES AND EXCHANGE COMMISSION

Issuer Delisting; Notice of Application to Withdraw From Listing and Registration; (Zevex International, Inc., Common Stock, $.001 Par Value) File No. 1–12965

November 16, 1998.

Zevex International, Inc. (''Company'') has filed an application with the Securities and Exchange Commission (''Commission''), pursuant to Section 12(d) of the Securities Exchange Act of 1934 (''Act'') and Rule 12d2–2(d) promulgated thereunder, to withdraw the above specified security (''Security'') from listing and registration on the American Stock Exchange, Inc. (''Amex'' or ''Exchange'').

The reasons cited in the application for withdrawing the Security from listing and registration include the following:

The Board of Directors of the Company unanimously approved a resolution on August 17, 1998, to withdraw the Company's Security from listing and registration on the Amex, because an application was being made to have the Security listed on Nasdaq. The Company began trading on Nasdaq on November 2, 1998.

The Company has complied with the rules of the Exchange by notifying the Amex of its intent to withdraw its Security from listing on the Exchange by letter dated September 22, 1998, and by providing the Exchange a copy of the certified Board of Director's resolution.

On September 23, 1998, the Exchange informed the Company that Amex would not interpose any objection to the action nor require the Company to send common stockholders any statement with respect thereto.

Any interested person may, on or before December 8, 1998, submit by letter to the Secretary of the Securities and Exchange Commission, 450 Fifth Street, N.W., Washington, D.C. 20549, facts bearing upon whether the application has been made in accordance with the rules of the Exchange and what terms, if any, should be imposed by the Commission for the protection of investors. The Commission, based on the information submitted to it, will issue an order granting the application after the date mentioned above, unless the Commission determines to order a hearing on the matter.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 98–31035 Filed 11–19–98; 8:45 am]

BILLING CODE 8010–01–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket OST–98–3680]

Application of Redemption, Inc. d/b/a Island Air Service for Issuance of New Certificate Authority

AGENCY: Department of Transportation.

ACTION: Notice of Order to Show Cause (Order 98–11–16).

SUMMARY: The Department of Transportation is directing all interested persons to show cause why it should not issue an order finding Redemption, Inc. d/b/a Island Air Service fit, willing, and able and awarding it a certificate of public convenience and necessity to engage in interstate scheduled air transportation of persons, property and mail.

RESPONSES: Objections and answers to objections should be filed in Docket OST–98–3680 and addressed to the Department of Transportation Dockets (SVC–124.1, Room PL–401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, and should be served on all persons listed in Attachment A to the order. Persons wishing to file objections should do so no later than November 30, 1998.

FOR FURTHER INFORMATION CONTACT: Mr. James Lawyer, Air Carrier Fitness Division (X–56, Room 6401), U.S. Department of Transportation, 400 Seventh Street, SW., Washington, DC 20590, (202) 366–9721.

Dated: November 16, 1998.

Patrick V. Murphy,

Deputy Assistant Secretary for Aviation and International Affairs.

[FR Doc. 98–31028 Filed 11–19–98; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Aviation Rulemaking Advisory Committee Meeting on Air Carrier Operations

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of meeting.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of the Federal Aviation Administration Aviation Rulemaking Advisory Committee to discuss air carrier operations issues.

DATES: The meeting will be held on December 15, 1998, at 1:00 p.m.

ADDRESSES: The meeting will be held at the Department of Transportation Building (Nassif Bldg.), Room 7332, 400 Seventh Street, SW., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Linda Williams, Office of Rulemaking, 800 Independence Avenue, SW., Washington, DC 20591, telephone (202) 267–9685.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C. App II), notice is hereby given of a meeting of the Aviation Rulemaking Advisory Committee to be held on December 15, 1998. The agenda for this meeting will include status reports on Fatigue Countermeasures Working Group, the Airplane Performance Working Group, and, possibly, a recommendation from the Reserve Duty/Rest Requirements Working Group. Attendance is open to the interested public but may be limited by the space available. The Members of the public must make arrangements in advance to present oral statements at the meeting or may present written statements to the committee at any time. Arrangements may be made by contacting the person listed under the

heading **FOR FURTHER INFORMATION CONTACT**.

Sign and oral interpretation can be made available at the meeting, as well as an assistive listening device, if requested 10 calendar days before the meeting.

Issued in Washington, DC, on November 16, 1998.

Quentin J. Smith, Jr.,

Assistant Executive Director for Air Carrier Operations, Aviation Rulemaking Advisory Committee.

[FR Doc. 98–31027 Filed 11–19–98; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

Amtrak Reform Council; Notice of Meeting

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of Amtrak Reform Council meeting.

SUMMARY: As provided in Section 203 of the Amtrak Reform and Accountability Act of 1997, the Federal Railroad Administration (FRA) gives notice of a meeting of the Amtrak Reform Council (''ARC''). The purpose of the meeting is to receive a briefing from the Department of Transportation's Inspector General regarding the independent assessment of Amtrak's financial needs and to take up such other matters as the Council or its members deem appropriate.

DATES: The ARC meeting is scheduled for 9:00 a.m. to 12:00 p.m. EST on Tuesday, November 24, 1998.

ADDRESSES: The meeting will be held in Krieble Center, Free Congress Foundation, 717 Second Street, NE, Washington, DC. The meeting is open to the public on a first-come, first-served basis. Portions of the meeting may be closed to the public at the discretion of the Council if proprietary information is to be discussed. Persons in need of special arrangements should contact the person whose name is listed below.

FOR FURTHER INFORMATION CONTACT: Alexander Chavrid, Passengers Programs Division, Office of Railroad Development, FRA, RDV–13, Mail Stop 20, 1120 Vermont Avenue, NW, Washington, DC 20590 (mailing address only) or by telephone at (202) 493–6380.

SUPPLEMENTARY INFORMATION: The ARC was created by the Amtrak Reform and Accountability Act of 1997 (ARAA) as an independent commission to evaluate Amtrak's performance and make recommendations to Amtrak for achieving further cost containment and productivity improvements, and financial reforms. In addition, the ARAA requires: that the ARC monitor cost savings resulting from work rules established under new agreements between Amtrak and its labor unions; that the ARC provide an annual report to Congress that includes an assessment of Amtrak's progress on the resolution of productivity issues; and that after two years the ARC begin to make findings on whether Amtrak can meet certain financial goals and, if not, to notify the President and the Congress.

The ARAA provides that the ARC consist of eleven members, including the Secretary of Transportation and ten others nominated by the President or Congressional leaders. Each member is to serve a 5 year term.

Issued in Washington, DC on November 17, 1998.

Mark E. Yachmetz,

Chief, Passenger Programs Division.

[FR Doc. 98–31058 Filed 11–19–98; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Docket Nos. S. MC–F–20937 and MC–F–20939] [1]

Coach USA, Inc., and Coach USA Northeast, Inc.—Control—Bonanza Bus Lines, Inc. and Coach USA North Central, Inc.—Control—Central Cab Company and Mountaineer Coach, Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice tentatively approving finance transactions.

SUMMARY: Coach USA, Inc. (Coach), a noncarrier, and its wholly owned noncarrier subsidiaries, Coach USA Northeast, Inc. (Northeast), and Coach USA North Central, Inc. (North Central) (collectively, applicants), filed an application [2] under 49 U.S.C. 14303 for Northeast to acquire control of Bonanza Bus Lines, Inc. (Bonanza), a motor passenger carrier, and for North Central to acquire control of Central Cab Company (Central Cab) and Mountaineer Coach, Inc. (Mountaineer), both motor passenger carriers. Persons wishing to oppose the applications must follow the rules under 49 CFR 1182.5 and 1182.8.[3] The Board has tentatively approved the transactions, and, if no opposing comments are timely filed, this notice will be the final Board action.

DATES: Comments must be filed by January 4, 1999. Applicants may file a reply by January 19, 1999. If no comments are filed by January 4, 1999, this notice is effective on that date.

ADDRESSES: Send an original and 10 copies of any comments referring to STB Docket No. MC–F–20937, *et al.* to: Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW, Washington, DC 20423–0001. In addition, send one copy of comments to applicants' representatives: Betty Jo Christian and David H. Coburn, Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW, Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Beryl Gordon, (202) 565–1600. [TDD for the hearing impaired: (202) 565–1695).]

SUPPLEMENTARY INFORMATION: In *Coach USA, Inc., and Coach USA North Central, Inc.—Control—Nine Motor Passenger Carriers*, STB Docket No. MC–F–20931, *et al.* (STB served Nov. 19, 1998), we approved, subject to comments, Coach's transfer of direct control of Coach-controlled motor passenger carriers to six noncarrier subsidiaries: North Central, Northeast, Coach USA South Central, Inc., Coach USA Southeast, Inc., Coach USA West, Inc., and Yellow Cab Service Corporation. While Coach will remain the sole owner of all of the stock of the subsidiaries, and will indirectly control the operating carriers, the subsidiaries will directly control the existing and future operating carriers of Coach.

Coach currently controls 73 motor passenger carriers. In STB Docket No. MC-F-20937, Coach and Northeast seek control of Bonanza.[4] In STB Docket No.

[1] These proceedings are not consolidated. A single decision is being issued for administrative convenience.

[2] Applicants filed a single pleading. Although the proposed control transactions are unrelated, applicants sought approval in a single application which embraced both transactions. Each transaction has been separately docketed.

[3] Revised procedures governing finance applications filed under 49 U.S.C. 14303 were adopted in *Revisions to Regulations Governing Finance Applications Involving Motor Passenger Carriers*, STB Ex Parte No. 559 (STB served Sept. 1, 1998).

[4] Bonanza is a Rhode Island corporation. It holds federally issued operating authority in Docket No. MC–13028, which authorizes it to provide regular-route operations between various points in New England and between points in New England to points in New York, and charter and special operations between points in the United States. It also holds authority issued by the Rhode Island Division of Public Utitilies and Carriers, the Connecticut Department of Transportation, and the Massachusetts Department of Public Utilities to conduct intrastate operations. It operates 54 buses; employs approximately 150 persons; and earned gross annual revenues in fiscal year 1997 of approximately $19 million. Prior to the transfer of its stock into a voting trust, it was owned by George M. Sage.

MC-F–20939, Coach and North Central seek control of Central Cab [5] and Mountaineer.[6] The acquisitions of control will be accomplished through the acquisition of all of the stock of each carrier. According to applicants, the stock is currently held in independent voting trusts to avoid any unlawful control pending disposition of this proceeding.

Coach submits that there will be no transfer of any federal or state operating authorities held by any of the carriers to be acquired. Following the consummation of the control transactions, each of these carriers will continue operating in the same manner as before and, according to Coach, granting the applications will not reduce competitive options available to the traveling public. Coach asserts that the carriers to be acquired do not compete to any meaningful degree with one another, are relatively small, and each faces substantial competition from other bus companies and transportation modes.

Coach also submits that granting the application will produce substantial benefits, including interest cost savings from the restructuring of debt and reduced operating costs from Coach's enhanced volume purchasing power. Specifically, Coach claims that each carrier to be acquired will benefit from the lower insurance premiums negotiated by Coach and from volume discounts for equipment and fuel. Applicants indicate that Coach or the relevant subsidiary will provide each of the carriers to be acquired with centralized legal and accounting functions and coordinated purchasing services. In addition, applicants state that vehicle sharing arrangements will be facilitated to ensure maximum use and efficient operation of equipment and that coordinated driver training services will be provided. Applicants also state that the proposed transactions will benefit the employees of each of the carriers to be acquired and that all collective bargaining agreements will be honored by Coach and the subsidiaries.

Coach plans to acquire control of additional motor passenger carriers in the coming months. It asserts that the financial benefits and operating efficiencies will be enhanced further by these subsequent transactions. Over the long term, Coach states that it will provide centralized marketing and reservation services for the bus firms that it controls, thereby enhancing the benefits resulting from these control transactions.

Applicants certify that: (1) the jurisdictional threshold has been met with respect to the transactions that are the subject of the applications; [7] (2) none of the carriers to be acquired holds an unsatisfactory safety rating from the U.S. Department of Transportation; [8] (3) each of the carriers to be acquired has sufficient liability insurance; (4) none of the carriers to be acquired is domiciled in Mexico or owned or controlled by persons of that country; and (5) approval of the transactions will not significantly affect either the quality of the human environment or the conservation of energy resources. Additional information may be obtained from the applicants' representatives.

Under 49 U.S.C. 14303(b), we must approve and authorize a transaction we find consistent with the public interest, taking into consideration at least: (1) the effect of the transaction on the adequacy of transportation to the public; (2) the total fixed charges that result; and (3) the interest of affected carrier employees.

On the basis of the applications, we find that the proposed acquisitions of control are consistent with the public interest and should be authorized. If any opposing comments are timely filed, this finding will be deemed vacated and, unless a final decision can be made on the record as developed, a procedural schedule will be adopted to reconsider the applications.[9] If no opposing comments are filed by the expiration of the comment period, this decision will take effect automatically and will be the final Board action.

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

It Is Ordered

1. The proposed acquisitions of control are approved and authorized, subject to the filing of opposing comments.

2. If timely opposing comments are filed, the findings made in this decision will be deemed as having been vacated.

3. This decision will be effective on January 4, 1999, unless timely opposing comments are filed.

4. A copy of this notice will be served on: (1) the U.S. Department of Transportation, Office of Motor Carriers-HIA 30, 400 Virginia Avenue, SW, Suite 600, Washington, DC 20024; and (2) the U.S. Department of Justice, Antitrust Division, 10th Street & Pennsylvania Avenue, NW, Washington, DC 20530.

Decided: November 12, 1998.

By the Board, Chairman Morgan and Vice Chairman Owen.

Vernon A. Williams,

Secretary.

[FR Doc. 98–31093 Filed 11–19–98; 8:45 am]

BILLING CODE 4915–00–P

[5] Central Cab is a Pennsylvania corporation. It holds federally issued operating authority in Docket No. MC–133058, which authorizes it to provide regular-route common carrier charter and special operations between points in the United States (except Hawaii). It also holds authority issued by the Pennsylvania Public Utility Commission, the Public Service Commission of West Virginia, and the Public Utilities Commission of Ohio to conduct intrastate operations. It operates approximately 34 motorcoaches, 11 school buses, and 9 vans; employs 96 persons; and earned gross annual revenues in fiscal year 1997 of approximately $4.7 million. Prior to the transfer of its stock into a voting trust, it was owned by John L. McNelly.

[6] Mountaineer is a Pennsylvania corporation. It holds federally issued operating authority in Docket No. MC–229627, which authorizes it to provide charter and special operations between points in the United States (except Alaska and Hawaii). It also holds authority issued by the Public Utilities Commission of West Virginia to conduct intrastate operations. It operates 6 motorcoaches and 2 vans; employs 28 persons; and earned gross annual revenues in fiscal year 1997 of approximately $1.1 million. Prior to the transfer of its stock into a voting trust, it was owned by John L. McNelly.

[7] *See* 49 CFR 1182.2(a)(5).

[8] Bonanza and Central Cab each hold a satisfactory rating; Mountaineer has not been rated.

[9] Under revised 49 CFR 1182.6(c), a procedural schedule will not be issued if we are able to dispose of opposition to the application on the basis of comments and the reply.

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33678]

Emons Transportation Group, Inc., and Emons Railroad Group, Inc.—Continuance in Control Exemption—St. Lawrence & Atlantic Railroad (Quebec) Inc.

AGENCY: Surface Transportation Board.

ACTION: Notice of exemption.

SUMMARY: Under 49 U.S.C. 10502, the Board exempts from the prior approval requirements of 49 U.S.C. 11323–25 the continuance in control by Emons Transportation Group, Inc., and Emons Railroad Group, Inc., of St. Lawrence & Atlantic Railroad (Quebec) Inc. upon that entity's becoming a Class III rail common carrier.

DATES: The exemption will be effective November 30, 1998. Petitions for stay must be filed by November 25, 1998, and petitions for reconsideration must be filed by December 21, 1998.

ADDRESSES: Send an original and 10 copies of all pleadings referring to STB Finance Docket No. 33678 to: Surface Transportation Board, Office of the

Secretary, Case Control Unit, 1925 K Street, NW, Washington, DC 20423–0001. In addition, send one copy of pleadings to petitioners' representative: Kevin M. Sheys, Oppenheimer Wolff Donnelly & Bayh LLP, 1350 Eye Street, NW, Suite 200, Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar (202) 565–1600. [TDD for the hearing impaired (202) 565–1695.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. To purchase a copy of the full decision, write to, call, or pick up in person from: DC News & Data, Inc., 1925 K Street, NW, Suite 210, Washington, DC 20006. Telephone: (202) 289–4357. [Assistance for the hearing impaired is available through TDD services (202) 565–1695.] Board decisions and notices are available on our website at WWW.STB.DOT.GOV.

Decided: November 13, 1998.

By the Board, Chairman Morgan and Vice Chairman Owen.

Vernon A. Williams,

Secretary.

[FR Doc. 98–31092 Filed 11–19–98; 8:45 am]

BILLING CODE 4915–00–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 33610]

Norfolk Southern Railway Company—Lease and Operation Exemption—Union Pacific Railroad Company

AGENCY: Surface Transportation Board.

ACTION: Notice of exemption.

SUMMARY: Under 49 U.S.C. 10502, the Board exempts from the requirements of 49 U.S.C. 11323–25 the lease and operation by Norfolk Southern Railway Company, successor by merger to Norfolk and Western Railway Company, of approximately 4.7 miles of Union Pacific Railroad Company's line between Monterey Lead Milepost 4.4 at Monterey Mine No. 1, near Carlinville, IL, and Monterey Lead Milepost 0.0 at Monterey Junction, IL, and a leg of the wye track and related trackage between mileposts 104.5 and 104.8 at Monterey Junction,[1] subject to standard labor protective conditions.

[1] On September 9, 1998, NSR simultaneously filed a petition for exemption wherein it proposed to purchase from Union Pacific Railroad Company and to operate approximately 15.3 miles of rail line between milepost 104.8 at Monterey Junction (including the southwest leg of the wye track at Monterey Junction, which is approximately between milepost 104.5 and milepost 104.8) and milepost 119.8 at DeCamp, IL, plus certain yard tracks at Madison, IL. That petition was granted in *Norfolk Southern Railway Company, Successor by Merger to Norfolk and Western Railway Company—Purchase—Union Pacific Railroad Company*, STB Finance Docket No. 33609 (STB served Oct. 29, 1998).

DATES: The exemption will be effective on December 16, 1998. Petitions to stay must be filed by December 2, 1998. Petitions to reopen must be filed by December 7, 1998.

ADDRESSES: An original and 10 copies of all pleadings referring to STB Finance Docket No. 33610 must be filed with the Surface Transportation Board, Office of the Secretary, Case Control Unit, 1925 K Street, NW, Washington, DC 20423–0001; in addition, a copy of all pleadings must be served on petitioner's representative: James R. Paschall, Three Commercial Place, Norfolk, VA 23510–2191.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 565–1600. [TDD for the hearing impaired: (202) 565–1695.]

SUPPLEMENTARY INFORMATION: Additional information is contained in the Board's decision. To purchase a copy of the full decision, write to, call or pick up in person from: DC NEWS & DATA, INC., 1925 K Street, NW, Suite 210, Washington DC 20006. Telephone: (202) 289–4357. [Assistance for the hearing impaired is available through TDD services (202) 565–1695.]

Board decisions and notices are available on our website at ''WWW.STB.DOT.GOV.''

Decided: November 12, 1998.

By the Board, Chairman Morgan and Vice Chairman Owen.

Vernon A. Williams,

Secretary.

[FR Doc. 98–30984 Filed 11–19–98; 8:45 am]

BILLING CODE 4915–00–P

Corrections

Federal Register

Vol. 63, No. 224

Friday, November 20, 1998

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 981104276–8276–01; I.D. 100898A]

Fisheries of the Northeastern United States; Proposed 1999 Fishing Quotas for Atlantic Surf Clams and Ocean Quahogs

Correction

In proposed rule document 98–30288, beginning on page 63434, in the issue of Friday, November 13, 1998, make the following correction:

On page 63434, in the second column, in the **DATES:** section, on the second line, ''December 17, 1998'' should read ''December 7, 1998''.

BILLING CODE 1505-01-D

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-4369-N-11]

Notice of Proposed Information Collection for Public Comment Consolidated Planning

Correction

In notice document 98–30482, beginning on page 63741, in the issue of Monday, November 16, 1998, make the following correction:

On page 63741, in the third column, under the heading **DATES:**, ''1998'' should read ''1999''.

BILLING CODE 1505-01-D

INTERNATIONAL DEVELOPMENT COOPERATION AGENCY

U.S. Agency for International Development

48 CFR Part 742

[AIDAR Notice 98-2]

Miscellaneous Amendments to Acquisition Regulations

Correction

In proposed rule document 98–28804 beginning on page 59501 in the issue of November 4, 1998, make the following corrections:

1. On page 59501, in the third column, in the fifth line from the bottom ''reduce'' should read ''induce''.

2. On the same page in the same column, in the last line, ''provision'' should be added after ''withholding''.

3. On page 59502, in the first column, in the second full paragraph, in the 20th line ''gown'' should read ''grown''.

742.1170-1 [Corrected]

742.1170-1 General.

4. On page 59503, in the second column, the section heading should read as set forth above.

742.1170-3 [Corrected]

5. On page 59504, in the first column, in 742.1170-3(c), in the fifth line from the bottom ''the claims'' should read ''the scope or terms of the contract or may result in claims''.

BILLING CODE 1505-01-D

Federal Register

Friday
November 20, 1998

Part II

Department of Labor

Employment Standards Administration

Wage and Hour Division

Guidance to All Government Contracting Agencies of the Federal Government and the District of Columbia Concerning Application of Davis-Bacon Wage Determinations to Contracts With Option Clauses; Notice

DEPARTMENT OF LABOR

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Guidance to All Government Contracting Agencies of the Federal Government and the District of Columbia Concerning Application of Davis-Bacon Wage Determinations to Contracts With Option Clauses

AGENCY: Wage and Hour Division, Employment Standards Administration, Labor.

ACTION: Notice.

SUMMARY: The Wage and Hour Division is publishing its guidelines concerning the circumstances in which the exercise of a contract option requires a new wage determination under the Davis-Bacon and related Acts.

FOR FURTHER INFORMATION CONTACT: Timothy Helm, Office of Enforcement Policy, Government Contracts Team, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, Room S–3018, 200 Constitution Avenue, NW, Washington, DC 20210. Telephone (202) 693–0064. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: In order to provide consistent enforcement and administration with respect to the Davis-Bacon and related Acts, Reorganization Plan No. 14 of 1950, 5 U.S.C. appendix, gives the Secretary of Labor the authority to prescribe regulations, standards, and procedures which are required to be observed by the contracting agencies. The Secretary has delegated such authority to the Wage and Hour Division. This includes the authority to interpret the Davis-Bacon and related Acts and the inherent authority to issue interpretive guidelines embodied in All Agency Memoranda informing the public of the standards the Wage and Hour Division intends to apply in the administration of the Davis-Bacon and related Acts.

Pursuant to this authority, the Wage and Hour Division issued on November 9, 1992, All Agency Memorandum No. 157 (AAM 157), which clarifies the application of Davis-Bacon wage determinations to federally-funded and assisted construction contracts that contain option clauses. The Wage and Hour Division, pursuant to its normal, customary practice, endeavored to send AAM 157 to all known government contracting agencies of the federal government and the District of Columbia.

By decision in ARB Case No. 96–133, dated July 17, 1997, the Administrative Review Board (ARB), which speaks finally on behalf of the Secretary concerning matters arising under the Davis-Bacon and related Acts, directed the Wage and Hour Division to publish AAM 157 in the **Federal Register**. AAM 157 is hereby published in the **Federal Register** in order to inform the public of the circumstances in which the exercise of an option provided in a contract governed by the Davis-Bacon and related Acts requires a new wage determination.

In addition, the ARB directed the Wage and Hour Division to provide clarification to AAM 157 in accordance with the discussion that was contained in the Administrator's ruling of May 2, 1996, that was the basis for the ARB decision.

In issuing AAM 157, the Department of Labor does not assert that the exercise of an option constitutes a new contract in all cases, without consideration of the specific contract requirements. For example, the Department does not consider that a new contract has been created in situations where a contractor is simply given additional time to complete its original contractual obligations. This situation is distinguishable, however, from a situation where an option is exercised obligating a contractor to perform work for a period of time for which it was not obligated under the terms of the original contract. In such an event, the Department considers that a new contract has been created for purposes of issuing a new wage determination.

Document Preparation

This document was prepared under the direction and control of John R. Fraser, Acting Administrator, Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor.

Signed at Washington, DC, this 13th day of November 1998.

John R. Fraser,

Acting Administrator, Wage and Hour Division.

U.S. Department of Labor

Employment Standards Administration, Wage and Hour Division, Washington, DC 20210

DEC. 9, 1992

MEMORANDUM NO. 157

TO: All Government Contracting Agencies of the Federal Government and the District of Columbia

FROM: Karen R. Keesling, Acting Administrator

SUBJECT: Application of Davis-Bacon Wage Determinations to Contracts with Option Clauses

This memorandum clarifies the application of Davis-Bacon wage determination to federally-funded and assisted construction contracts that contain option clauses, and to federal service contracts which have a substantial and segregable amount of construction work that require the application of the Davis-Bacon Act and which also contain option clauses. Some contracting agencies have not been incorporating a new or current Davis-Bacon wage determination in these contracts at the time an option is exercised. To ensure consistency, we are providing the following guidance on this subject.

The Davis-Bacon Act applies to ''every *contract* in excess of $2,000, to which the United States or the District of Columbia is a party, for the construction, alteration, and/or repair, including painting and decorating, of public buildings or public works.'' (Emphasis added.)

Multi-year construction contracts that contain option provisions by which a contracting agency may unilaterally extend the term of the contract require inclusion of a current wage determination at the time the option is exercised. This requirement is consistent with the purpose of the Davis-Bacon Act to ensure that employees be paid prevailing wages, and the McNamara-O'Hara Service Contract Act (SCA) regulations governing option periods under that statute. As explained in section 4.145(a) of Regulations, 29 CFR Part 4, the exercise of such an option requires a contractor to perform work for a period of time for which it would not have been obligated—and for which the government would not have been required to pay—under the terms of the original contract if the option had not been exercised. Thus, once the option on a contract is exercised, the additional period of performance becomes a new contract.

Accordingly, every federally-funded or assisted multi-year construction contract in excess of $2,000 that contains a provision to extend an existing contract—pursuant to an option clause or otherwise—so that the construction is performed over an extended period of time (as opposed to situations where a contractor is given additional time to complete its original contract commitment), must include a current Davis-Bacon wage determination. Similarly, just as a current SCA wage determination must be incorporated at the exercise of an option in an SCA contract, if an option in the SCA contract calls for substantial and segregable construction work, then a current Davis-Bacon wage determination must also be incorporated at the exercise of the option.

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Friday
November 20, 1998

Part III

Department of the Treasury

Fiscal Service

31 CFR Parts 317, 351, 353, and 370

Regulations Governing Agencies for the Issue and Offering of United States Savings Bonds, Including Sales by Electronic Means; Final Rule

DEPARTMENT OF THE TREASURY

Fiscal Service

31 CFR Parts 317, 351, 353, and 370

Regulations Governing Agencies for the Issue and Offering of United States Savings Bonds, Including Sales by Electronic Means

AGENCY: Bureau of the Public Debt, Fiscal Service, Treasury.

ACTION: Final rule.

SUMMARY: The Department of the Treasury hereby publishes a final rule governing the issue and offering of United States Savings Bonds. The final rule creates new categories of savings bond issuing agents and clarifies and expands the means by which savings bonds may be sold, including electronic means.

DATES: Effective November 20, 1998.

ADDRESSES: This final rule can be downloaded from the Bureau of the Public Debt at the following World Wide Web address: <http://www.savingsbonds.gov>. It also is available for public inspection and copying at the Treasury Department Library, Freedom of Information Act (FOIA) Collection, Room 5030, Main Treasury Building, 1500 Pennsylvania Ave. NW, Washington, D.C. 20220. Individuals wishing to visit the library should call (202) 622–0990 for an appointment.

FOR FURTHER INFORMATION CONTACT: Wallace L. Earnest, Director, Division of Staff Services, Savings Bond Operations Office, Bureau of the Public Debt, at (304) 480–6319 or <wearnest@bpd.treas.gov>; Troy D. Martin, Senior Program Analyst, Savings Bond Operations Office, Bureau of the Public Debt, Division of Staff Services, at (304) 480–6545 or <tmartin@bpd.treas.gov>; Edward C. Gronseth, Deputy Chief Counsel, Bureau of the Public Debt, at (304) 480–5192 or <egronseth@bpd.treas.gov>; or Gregory J. Till, Attorney-Adviser, Office of the Chief Counsel, Bureau of the Public Debt, at (202) 219–3320 or <gtill@bpd.treas.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

The growth of electronic commerce and the World Wide Web have led to a flourishing of financial service providers and new payment methods. However, the Bureau of the Public Debt has been unable to take full advantage of these developments in the sale of United States Savings Bonds because of apparent restrictions in existing regulations.

On April 30, 1998, the Department of the Treasury published a proposed rule addressing the issue and offering of United States Savings Bonds. The publication proposed to create new categories of savings bond issuing agents and clarify and expand the means by which savings bonds may be sold, including electronic means. Three written comment letters were received in response to the proposed rule. The proposed rule and comments can be downloaded from the Bureau of the Public Debt at the following World Wide Web address: <http://www.savingsbonds.gov>. Treasury found the comments extremely useful in making revisions. Although some minor comments are not addressed, all comments have been considered in the formulation of this final rule. The comments are addressed below on a section-by-section basis.

The most important aspects of the final rule are directed at four areas in title 31 of the Code of Federal Regulations. First, changes in §§ 317.2 and 317.3 amend the regulations used to determine which organizations may serve as issuing agents and the procedures used to qualify these organizations as issuing agents. Second, changes to § 351.5 expand the means by which issuing agents may sell savings bonds. Third, a new subpart in part 370 addresses the use of Automated Clearing House debit entries for the sale of savings bonds issued through the Bureau of the Public Debt. Fourth, another new subpart in part 370 addresses the electronic submission of transaction requests through the Bureau of the Public Debt.

II. Summary of Amendments

A. Regulations Governing Agencies for Issue of Savings Bonds (31 CFR Part 317)

(1) Definitions (§ 317.1)

The revised definition of ''issuing agent'' notes the authority of the Commissioner of the Public Debt to qualify issuing agents, as explained in § 317.2. The definition also clarifies that an issuing agent acts as an agent of the purchaser in handling the remittance. The language addressing the handling of the remittance is consistent with current practice. The Secretary of the Treasury collects purchase funds from issuing agents, not the public. If an issuing agent discovers that the remittance is uncollectible or must be returned after the issuance of a savings bond, the Secretary is nonetheless entitled to payment from the issuing agent. The issuing agent bears the risk of loss for non-collection or return of the remittance.

(2) Organizations Eligible To Serve as Issuing Agents (§ 317.2)

In the past, issuing agent eligibility has been limited to financial institutions (such as banks and credit unions), agencies of the United States and state and local governments, and employers operating payroll savings plans. This final rule expands the types of organizations that are eligible to serve as issuing agents.

One change, in § 317.2(c), allows organizations that operate payroll savings plans on behalf of employers to issue bonds and serve as issuing agents. The change is designed to bolster payroll savings plan sales from small businesses, which often do not have the resources to maintain such plans themselves. As is the case with employer organizations, an organization operating a payroll savings plan on behalf of an employer organization will be eligible for issuing agent fees only if it inscribes savings bonds.

Another addition, set out in § 317.2(d), gives the Commissioner of the Bureau of the Public Debt the authority to qualify issuing agents when doing so is in the public interest. The Commissioner can use such process as deemed to be appropriate in selecting the issuing agent. The selected issuing agent also will be subject to such conditions as deemed to be appropriate.

The new § 317.2(d) will be used for the selection of entities to sell savings bonds in unique ways as new methods of sales emerge. In particular, this provision will facilitate the qualification of issuing agents to sell savings bonds through electronic methods, such as those offered by financial services providers through World Wide Web access. In qualifying issuing agents under this provision, the Commissioner will balance the convenience and cost-effectiveness of using new purchase methods against the need to insure the security and reliability of those methods.

In its comment letter, the American Bankers Association indicated its general support for most of the changes being proposed but expressed concern over Section 317.2(d), stating, ''There is no demonstrable need to add this text given the capabilities and interest of currently eligible organizations.'' Treasury recognizes the long-standing service of financial institutions as issuing agents of savings bonds and the significant contribution that financial institutions have made toward the success of the savings bond program.

Treasury also looks forward to cooperating with financial institutions in selling savings bonds in new ways. In particular, Treasury is interested in selling savings bonds through home banking packages offered by financial institutions and exploring other new methods which may evolve over time. However, changes are taking place rapidly in other sectors of the savings bonds market place, and in particular, in portions of the market place not exclusively the domain of financial institutions which makes necessary the flexibility afforded by section 317.2(d). Therefore, Treasury respectfully disagrees with the position that the flexibility to be gained through section 317.2(d) would not benefit the savings bond program, and has decided to retain the provision in the final rule.

(3) Procedures for Qualifying and Serving as an Issuing Agent (§ 317.3)

In the past, designated Federal Reserve Banks have processed applications from prospective issuing agents. The section has been amended to state that an organization that seeks qualification because of its status as an organization operating a payroll savings plan on behalf of an employer under § 317.2(c) or under the general ''public interest'' provision of § 317.2(d) will apply directly to the Commissioner of the Bureau of the Public Debt. The application shall be supplemented by such other information as the Bureau of the Public Debt may request.

(4) Issuance of Bonds (§ 317.6)

The issuing agent fee provision has been simplified by removing unnecessary detail. The section continues to emphasize that fee schedules are set out not in the regulations, but through a separate publication in the **Federal Register**. The changes have no effect on the current fee structure, though the Bureau of the Public Debt reserves the right to create new categories of fees as new ways of selling savings bonds develop.

(5) Appendix to § 317.8—Remittance of Sales Proceeds and Registration Records, Department of the Treasury Circular, Public Debt Series No. 4–67 (Third Revision), Fiscal Service, Bureau of the Public Debt

The appendix has been revised, primarily for changes in terminology. For instance, the definition of ''issuing agent'' has been redefined to reflect the changes to that term in § 317.2. The term ''over-the-counter'' has been redefined to reflect the expanded meaning given to that term in § 351.5 of this chapter. Among other minor changes, paragraph (3) of subpart B has been removed because that provision no longer has application.

B. Offering of United States Savings Bonds, Series EE (31 CFR Part 351)

(1) Governing Regulations for Series EE Bonds (§ 351.1)

This section has been amended to note that the regulations governing the transfer of funds by electronic means on account of United States securities in part 370 of this chapter apply to transactions for the purchase of savings bonds issued through the Bureau of the Public Debt. The regulations in part 370 have no application to transactions for the purchase of savings bonds accomplished through issuing agents generally, unless and to the extent otherwise directed by the Commissioner of the Bureau of the Public Debt. Furthermore, because these regulations are intended to be the source of the terms and conditions of Series EE bonds, Treasury does not warrant the correctness of representations that in any way conflict with these regulations.

(2) Purchase of Bonds (§ 351.5)

The categories of savings bond sales provided for in this section have been revised. The section previously provided for four categories of sales: (1) ''payroll plans''; (2) ''over-the-counter/mail''; (3) ''bond-a-month plan''; and (4) ''employee thrift, savings, vacation, and similar plans.'' Because some of these categories are limited and outdated, they may actually have inhibited rather than facilitated sales.

Furthermore, a comparison of this section to the appendix to § 317.8 of this chapter (discussing the remittance of sales proceeds and registration records by issuing agents) showed a lack of consistency in the categories and terminology used to define savings bond sales. In discussing savings bond sales, the appendix did not mirror § 351.5 but rather combined the four categories of sales described in § 351.5 into two categories: (1) ''payroll sale''; and (2) ''over-the-counter sale.'' The term ''payroll sale'' was not used in § 351.5. Also, the term ''over-the-counter'' had an expanded meaning in the appendix to § 317.8 as compared to its use in § 351.5, making the regulations more difficult to understand.

The final rule revises § 351.5 (as well as the appendix to § 317.8), essentially using the two categories in the appendix to § 317.8: (1) ''payroll sales''; and (2) ''over-the-counter sales.'' The payroll sales category includes sales through ''payroll savings plans'' and ''employee thrift, savings, vacation, and similar plans,'' the provisions of which are largely unchanged. The final rule also states that employers and the organizations operating payroll savings plans on behalf of employers are allowed to sell savings bonds only pursuant to payroll savings plans. These types of issuing agents are not allowed to sell savings bonds over-the-counter.

Over-the-counter sales are all sales that are not payroll sales. For over-the-counter sales, the section provides that ''the purchase application and remittance may be submitted to an issuing agent by any means acceptable to the issuing agent.'' This broad provision ensures that issuing agents have the flexibility to sell savings bonds through new channels. For instance, the final rule authorizes issuing agents to sell savings bonds through electronic means such as the World Wide Web. Both the application and remittance can be submitted and signed through electronic methods agreed upon by the parties.

The final rule does not impose limitations on the types of remittances that an issuing agent may accept. As always, however, the issuing agent bears the burden of collection and risk of non-collection for remittances it accepts. The Secretary of the Treasury takes payment from the issuing agent, not the purchaser. The Secretary of the Treasury has no obligation to return funds received from an issuing agent after issuance of a savings bond if the issuing agent cannot collect or must return the remittance. However, as Treasury qualifies new types of issuing agents under the revised section 317.2 of this chapter, Treasury will examine carefully the types of remittances each new issuing agent will accept and the protections that will be necessary to insure that a purchaser's funds reach Treasury in proper fashion.

Finally, although the changes have no effect on the current issuing agent fee structure, the Bureau of the Public Debt reserves the right to make changes to the fee structure as new ways of selling savings bonds develop.

C. Regulations Governing United States Savings Bonds, Series EE and HH (31 CFR Part 353)

(1) Payment to Judgment Creditors (§ 353.21)

This section is amended to state that savings bonds registered in coownership form may be subject to levy by the Internal Revenue Service.

(2) Application for Relief—Non-receipt of Bond (§ 353.27)

The regulations have provided little guidance as to the status of savings bond purchases if the Secretary of the Treasury does not receive payment. While not likely, an issuing agent may fail after receiving the remittance from a purchaser but before the Secretary collects the sales proceeds from the issuing agent.

If an issuing agent has inscribed a savings bond, the Secretary will honor the savings bond even if the Secretary cannot collect the sales proceeds from the issuing agent. This policy is consistent with existing regulations, which note that the registration of an issued savings bond generally is conclusive of ownership. If a savings bond has not been inscribed, the final rule states that the Secretary is authorized to issue savings bonds to preserve the public's confidence in dealing with issuing agents, even if the Secretary cannot collect the sales proceeds from the issuing agent.

D. Regulations Governing Electronic Transactions and the Transfer of Funds by Electronic Means on Account of United States Securities (31 CFR Part 370)

(1) Applicability (§ 370.0)

This section is amended to clarify that to the extent the regulations in part 210 of this title apply to the purchase or payment of interest and principal on United States securities, the regulations in this part 370 apply in the event of any inconsistencies. Furthermore, to the extent that Regulations E (12 CFR part 205) and Z (12 CFR part 226) of the Board of Governors of the Federal Reserve System (''Federal Reserve Board'' or ''Board'') apply to transactions accomplished pursuant to this part, those Federal laws are unaffected by this part. Regulations E and Z govern consumer rights for electronic funds transfers and credit card transactions, among other things. This part 370 is designed to compliment, not preempt, the rights a person has by recourse to the person's financial institution under Regulation E, to the extent that Regulation E applies.

A determination of whether Regulation E applies to a transaction for the purchase of a United States security frequently depends upon whether the security is held in book-entry or definitive form. Regulation E excludes from its coverage ''[a]ny transfer of funds the primary purpose of which is the purchase or sale of a security * * * [h]eld in book-entry form by a Federal Reserve Bank or federal agency,'' at 12 CFR 205.3(c)(4)(iii). This exclusion was added by the Federal Reserve Board in a final rule published in the **Federal Register** on May 2, 1996, beginning at page 19661. In discussing this exclusion, the Board listed as an example transactions involving book-entry securities held in TREASURY DIRECT. Because savings bonds currently available for purchase primarily are held in definitive rather than book-entry form, the strict language of this exclusion does not extend to most transactions involving savings bonds available for purchase.

(2) Definitions (§ 370.1)

Several definitions have been added or changed in this section. The definition of ''Automated Clearing House (ACH) entry'' refers to transactions accomplished in accordance with the Operating Rules and Guidelines of the National Automated Clearing House Association (''NACHA Rules''), as modified by these and other regulations and law. The definition of ''deposit account'' principally is taken from Regulation E. The definition of ''financial institution'' is the same as that included in a proposed rule to amend part 208 of this title, ''Management of Federal Agency Disbursements,'' published in the **Federal Register** on September 16, 1997, beginning at page 48714. The definitions of ''originator'' and ''person'' are derived from the NACHA Rules. Also, the definition of ''payment'' has been amended to state that it applies only to subpart B of this part, which addresses credit entries. The limited definition of a payment as a deposit from the Treasury to the account of the owner only has application in subpart B and may have caused confusion by its application throughout part 370.

The section also lists five definitions that have application primarily to subpart E of this part, addressing the electronic submission of transaction requests through the Bureau of the Public Debt. As noted in the discussion to § 370.50, Treasury has looked to a number of sources in drafting these provisions. The most fundamental of these definitions is that of a ''signature.'' A signature is ''any symbol or method executed or adopted by a party with present intention to be bound,'' which is a traditional legal definition of a signature. The definition encompasses a signature manifested through electronic or similar means, which separately is referred to as an ''electronic signature.'' Case law on signatures indicates that almost anything can constitute a signature, from printed and typewritten names to account numbers, if executed with an intent to be bound. Electronic signatures are no different from other forms of signatures in this regard.

In addition, the section includes a definition of ''digital signature,'' which is a type of electronic signature. Treasury will use digital signatures in its sales of savings bonds over the Internet. A digital signature uses ''public-key encryption'' and a ''message digest function'' in transforming an electronic ''record.'' The definitions of these terms largely are taken from model, proposed, or existing authorities.

Public-key encryption is a process that relies upon an algorithm to produce two mathematically related but different keys. If public-key encryption is implemented securely, it is computationally infeasible to derive one key from the other. The keys can be used for several purposes, including the creation and verification of digital signatures. One key (the private key) is kept private and can be used to create a digital signature, while the other key (the public key) may be distributed to anyone and can be used by a relying party to verify a digital signature. The association of a public key (and by implication, its corresponding private key) to the identity of a particular person is accomplished through the use of digital certificates, issued by certification authorities.

The use of a message digest function (also known as a hash function) is an essential element in the creation and verification of a digital signature. A message digest function is an algorithm that typically provides a shortened, mathematical version of a longer electronic record. Even a small change to an electronic record can result in a dramatic change to a message digest, aiding in the verification of a digital signature and any electronic record to which the signature is attached. The signer uses the signer's private key to encrypt the short message digest, rather than the entire electronic record. This digital signature (the message digest, encrypted by the signer's private key) is sent to the recipient, along with a copy of the electronic record.

Upon receipt of the digital signature and electronic record, the recipient uses the signer's public key to decrypt the digital signature and recover the message digest. The recipient then runs the received copy of the electronic record through the same message digest function used to create the received message digest. If the two results are identical, the recipient knows that the electronic record was encrypted by the signer's private key and that the electronic record was not tampered with

from the time the signer created the digital signature.

(3) Scope (§ 370.30)

This section states that subpart D establishes regulations for debit entries to a purchaser's account to buy savings bonds issued by the Bureau of the Public Debt. The subpart also establishes the exclusive liability of the Bureau of the Public Debt for such entries. This subpart applies only to transactions for the purchase of savings bonds issued through the Bureau of the Public Debt. These regulations do not apply to transactions for the purchase of savings bonds accomplished through issuing agents generally, unless and to the extent the Commissioner of the Bureau of the Public Debt deems otherwise.

It is anticipated that purchasers will authorize an entity named on an approved paper-based authorization form to be an originator for the debit entries. This entity will forward collected funds to Treasury (unless the Bureau of the Public Debt chooses to name itself as the originator). The Bureau of the Public Debt will then issue the savings bonds through a Federal Reserve Bank acting as a fiscal agent for the United States.

(4) Authorization (§ 370.31)

This section states that all debit authorizations must be accomplished through an authorization form approved by the Bureau of the Public Debt. The purchaser must name a deposit account from which the purchaser is entitled to withdraw funds, and the purchaser (as well as any other necessary persons named on the deposit account) must sign the authorization form. Except to the extent required by the Bureau of the Public Debt, the originator will not be required to verify the identity of the purchaser or the authenticity of any signatures. Recurring debits may or must be authorized if the form so provides. Also, a purchaser's subsequent authorization will cancel a previous authorization.

The Bureau of the Public Debt retains the right to name a successor to the originator without additional notice to the purchaser, though it may ask the successor to provide such notice as a customer service. This provision is drawn from the official staff interpretation of the Federal Reserve Board to 12 CFR 205.10(b) (Regulation E), which states that ''successor institutions'' may assume an originator's role without notice or a new authorization.

In their comment letters, the Federal Reserve Board and NACHA speculated that Treasury may eventually allow the submission of debit authorizations through electronic means. Part 370 could allow for the submission of debit authorizations through electronic means.

The Board and NACHA referenced provisions in Regulation E and the NACHA Rules addressing the electronic submission of debit authorizations. Neither Regulation E nor the NACHA Rules appear to allow for the electronic signature of debit authorizations. Regulation E requires that debit ACH authorizations be in a ''writing signed or similarly authenticated by the consumer,'' at 12 CFR 205.10(b). Section 2.1.2 of the NACHA Rules uses identical language. Under Regulation E and the NACHA Rules, an electronic debit ACH authorization is not ''signed,'' but rather is ''similarly authenticated.''

Treasury is not inclined to add the words ''similarly authenticated'' to this final rule. Treasury believes that its definition of ''signature'' would encompass electronic means which also would qualify under the ''similarly authenticated'' category of Regulation E and the NACHA Rules. Treasury recognizes that the Federal Reserve Board may interpret the definition of ''similarly authenticated'' more strictly than Treasury in its definition of ''signature.'' To address this concern, § 370.0 of this part has been amended to note that transactions accomplished under this part are subject to Regulation E, when applicable. Thus, even if a debit authorization for the purchase of a definitive savings bond could be electronically signed under this part, the electronic signature would have to meet the ''similarly authenticated'' requirements of Regulation E.

(5) Prenotification (§ 370.32)

The section leaves the requirement of a prenotification message to the discretion of the Bureau of the Public Debt. A financial institution that fails to respond to a prenotification warrants that the deposit account number and the type of account contained in the message is accurate as of the time of receipt of the prenotification. The proposed rule also would have left the time period in which a financial institution must respond to a prenotification up the Bureau of the Public Debt. In its comment letter, NACHA expressed the view that Treasury should not deviate from the NACHA Rules in setting its own time frame for a response. Treasury agrees with this suggestion and has changed this provision in the final rule to state that the time period for a response shall be that which is set out by NACHA.

(6) Warranties of Financial Institution (§ 370.33)

This section states that a financial institution's acceptance and handling of a debit entry or failure to reject a prenotification made with respect to a security covered by this subpart shall constitute its agreement to the provisions of this subpart. Also, a financial institution that agrees to this subpart warrants that it has the authority to receive entries and to comply with any requirements imposed upon Receiving Depository Financial Institutions under the Operating Rules and Operating Guidelines of the National Automated Clearing House Association, as modified by these and other regulations and law.

(7) Responsibilities of Financial Institution (§ 370.34)

This section states that a financial institution that receives a debit entry on behalf of its customer must debit the customer's account on the settlement date. If the financial institution is unable to debit the designated account, it shall return the entry by no later than the next business day after receipt, with an electronic message or other response explaining the reason for the return.

(8) Termination or Suspension by the Bureau of the Public Debt (§ 370.35)

This section states that the Bureau of the Public Debt can terminate or suspend the availability of debit entries at any time, and its decision to do so will be final.

(9) Termination or Suspension by Purchaser or Deposit Account Owner by Notice to the Originator (§ 370.36)

Under this section, a purchaser or deposit account owner will be able to cancel or suspend debit entries for the purchase of savings bonds by providing written or oral notice to the originator, which must be received by the originator within three days of the debit. The originator may require the person to give written confirmation within 14 days of an oral notice. An oral notice ceases to be effective if the written confirmation is not received by the end of the 14-day period. A suspension will remain in effect for the duration specified by the purchaser, but for no more than six months. As noted in § 370.53 of this part, a written notice can be accomplished through electronic means.

The proposed rule was similar, but would have required written notice in all cases. In its comment letter, the Federal Reserve Board suggested that Treasury follow the stop-payment provisions in Regulation E, at 12 CFR

§ 205.10(c). The provision noted by the Federal Reserve Board allows for the option of oral notice. Treasury finds this approach to be more flexible and agrees with the Federal Reserve Board recommendation. The substance of 12 CFR § 205.10(c), including provisions for oral notice, has been incorporated into the final rule.

(10) Changes and Error Resolution (§ 370.37)

This section provides that while responding to an oral or written notice from a person relating to the propriety of issuance information or a debit entry involving the person's deposit account, the originator may suspend further debit entries. In response to an oral notice, the originator may require the person to give written notice, to be received by the originator within 10 business days of an oral notice. The originator promptly will investigate and correct any error, but is not bound to complete the investigation or correct the error within 10 business days if the person fails to provide the requested written confirmation. As noted in § 370.53 of this part, a written notice can be accomplished through electronic means.

In its comment letter, the Federal Reserve Board focused on a provision of the proposed rule that would have allowed the originator to ignore an oral notice that was not received within 30 days of a written notice. The Board expressed the view that this provision varied from the error resolution procedures in Regulation E, at 12 CFR § 205.11. Treasury has decided to drop this questioned provision. Treasury also has changed the time frame for a written confirmation to 10 business days, consistent with Regulation E.

(11) Liability (§ 370.38)

This section states that the Bureau of the Public Debt is not liable in disputes arising out of debit entries, unless the Bureau of the Public Debt names itself or a fiscal or financial agent as the originator. Disputes arising out of debit entries are the responsibility of the originator. Also, unless the Bureau of the Public Debt designates itself or a fiscal or financial agent as the originator, the originator serves as the agent of the purchaser in handling the remittance. At most, liability of the Bureau of the Public Debt is limited to the amount of the improper debit, less any losses caused by the failure of a claimant to exercise due diligence.

(12) Scope (§ 370.50)

This section states that subpart E establishes provisions for the electronic submission of transaction requests through the Bureau of the Public Debt. The subpart also sets out the exclusive liability of the Bureau of the Public Debt for transactions completed pursuant to this subpart. These regulations do not apply to transactions requests accomplished through savings bond issuing agents generally, unless and to the extent the Commissioner of the Bureau of the Public Debt deems otherwise.

It is important to note the limited scope and extent of this subpart E. This subpart only sets out Federal contract law provisions for electronic dealings with the Bureau of the Public Debt. For instance, a person who purchases a security from or opens a securities account with the Bureau of the Public Debt agrees to these provisions. The subpart does not apply to savings bond sales accomplished through issuing agents such as banks and employers offering payroll savings plans. The regulations leave unchanged the right of states to determine their own rules for electronic and digital signatures and does not address any issues related to certification authorities. Furthermore, the regulations are relatively brief, at least in comparison to work done by the American Bar Association, the National Conference of Commissioners on Uniform State Laws, the American Law Institute, the United Nations Commission on International Trade Law, and many states, among others.

(13) Requirements (§ 370.51)

An electronically signed transaction request cannot be accepted by the Bureau of the Public Debt unless the signature has been accomplished through a method that has been approved for specific purposes by the Bureau of the Public Debt.

(14) Time of Acceptance (§ 370.52)

Acceptance of a transaction request by the Bureau of the Public Debt will be effective no earlier than upon receipt of the message by the Bureau of the Public Debt, and no later than upon the transmittal of a message of acceptance by the Bureau of the Public Debt.

(15) Point of Transaction (§ 370.53)

The point of transaction for a transaction request submitted electronically under this subpart will be Parkersburg, West Virginia.

(16) Effect of Electronic Signature (§ 370.54)

This section states that an electronic signature and any electronic record to which it is affixed shall not be denied legal effect, including legal effect as a signature, a writing, or an original, solely because the signature or record is in electronic form. Some provisions of law, such as the Statute of Frauds, require evidence of an agreement to be in writing. Other provisions of law require that an original record be produced in court, rather than a copy, or require that a record be signed. However, there seems little reason to use these doctrines to preclude the admissibility of electronically signed records. These records are equivalent to signed writings, each copy of which is identical to the original.

(17) Admissibility of Digital Signature (§ 370.55)

This section addresses the legal requirement that an item be authenticated before being introduced into evidence. ''Authentication'' is a term that has a technical meaning specifically linked to the security of electronic signatures, but also has a separate meaning in the law of evidence, at which this section is directed.

Under Rule 901 of the Federal Rules of Evidence, ''The requirement of authentication * * * as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that the matter in question is what its proponent claims.'' For instance, under Rule 901(b)(2), this evidentiary requirement may be met in regard to a handwritten record by nonexpert testimony as to the genuineness of handwriting. Although there have not as yet been any cases on the matter, the requirement of authentication for digital signatures likely can be met under Rule 901(b)(9), which allows for the sufficiency of ''[e]vidence describing a process or system used to produce a result and showing that the process or system produces such a result.''

However, in some situations authentication evidence is not required as a condition precedent to admissibility. As noted under Rule 902 of the Federal Rules of Evidence, extrinsic evidence of authenticity is not necessary for certified birth and death certificates, newspapers and periodicals, trade inscriptions, commercial paper, and notarized records, among other things. Because these items are likely to be authentic, a strict adherence to preliminary authentication procedures unnecessarily would expend a court's time and resources. Accordingly, the items are considered to be self-authenticating and—barring other objections to the evidence—may be admitted into evidence without additional preliminary review.

The section states a limited self-authentication provision for digital

signatures. This section begins by noting that authentication of a purported digital signature may be accomplished by evidence sufficient to support a finding that a digital signature exists. However, extrinsic evidence of authenticity is unnecessary to establish that a digital signature corresponds to a public key pair, as well as that an electronic record to which a digital signature is affixed has not been altered from its original form.

There are several reasons that support the insertion of a limited self-authentication clause into this final rule. If public-key encryption has been properly implemented, the risk of a successful forgery or alteration of a digital signature is extremely remote, and is significantly less than the risk of forgery or alteration for paper records. Furthermore, although a legal showing of authenticity in the absence of a self-authentication provision almost certainly could be accomplished, such a showing would require considerable time and resources. Among other things, it would entail extensive scientific testimony on encryption, leading to an expensive and unproductive ''battle of the experts.'' Use of a self-authentication provision avoids this wasteful problem.

In almost all cases, the existence of a digital signature should be beyond reasonable dispute. The most likely challenges to a digital signature and an electronic record to which it is affixed will turn not on whether a digital signature exists, but on whether the digital signature should be attributed to a particular person. These challenges frequently will focus on the issuance, protection, or revocation of the digital certificates used to link a digital signature and accompanying record to a particular person. This section does nothing to prevent such challenges, for the self-authentication provision does not tie a digital signature to a particular person. Extrinsic evidence tying the public key pair used in the creation of a digital signature to a particular person still will have to be provided before a digital signature and a record to which it has been affixed could be admissible. Furthermore, this section would have no application at all in criminal cases.

Finally, even to the extent that a self-authenticated digital signature and accompanying record could be introduced into evidence under this section, this section in no way prevents a party against whom a digital signature is asserted from contesting the existence or authenticity of the signature. However, any arguments would go to the weight of the evidence, not to its admissibility.

(18) Negligence Contributing to Forged Signature (§ 370.56)

This section states that a person whose failure to exercise ordinary care substantially contributes to the creation or submission of a forged signature is precluded from disavowing the forged signature. Furthermore, the burdens are on the person against whom a signature is asserted to produce evidence that ordinary care was exercised and to persuade a trier of fact that it is more likely than not that the person exercised ordinary care. However, in asserting a signature under this section the Bureau of the Public Debt first will have to establish that it exercised ordinary care in relying upon the signature.

This section is drawn in part from section 3–406 of the Uniform Commercial Code (UCC) (''Negligence Contributing to Forged Signature or Alteration of Instrument.''). The responsibilities imposed upon persons in regard to the technology used to create and submit electronic signatures and accompanying electronic records are similar to those imposed under the UCC in regard to rubber signature stamps used to sign checks. Official Comment 3 to UCC section 3–406 is enlightening in this regard. If a person's rubber signature stamp and checks, kept in an unlocked drawer, are stolen and used by a party to forge a check, a bank may successfully be able to argue that the person is precluded from disavowing the forged signature because the person's lack of ordinary care substantially contributed to the forgery. Similarly, under the final rule if a person fails to take adequate security precautions to protect access to electronic signature technology (such as by not safekeeping a computer password, for instance) and this failure substantially contributes to the creation or submission of a forged signature, the person is precluded from disavowing the signature.

By looking to the UCC provision, this section attempts to find middle ground between varying approaches in current law as to how liability should be distributed between the parties for unauthorized transactions. For instance, a person can be held accountable for all unauthorized calls from that person's telephone number, without regard to whether ordinary care was exercised by the person. At the other end of the spectrum, a person cannot be held accountable beyond $50 in unauthorized transactions on that person's credit card, regardless of whether the consumer exercised ordinary care in protecting the card or in promptly reporting a loss or theft of the card.

Treasury believes that if pursued in these regulations, a provision that allows the assertion of a forged signature against a person even if the person exercised ordinary care would unfairly punish consumers and discourage electronic commerce. At the same time, if a person's fault has led to the creation of a forged signature, a provision that limits or precludes the assertion of the signature against the person does little to encourage the exercise of ordinary care. This section allows the assertion of a forged signature only if the person's failure to exercise ordinary care substantially contributed to the creation of the signature.

This section places the burdens of production and persuasion upon the person against whom the signature would be asserted to show that the person exercised ordinary care. Because an electronic signature is not created in the presence of the person accepting the signature, the person accepting the signature typically does not have best access to the evidence needed to establish the forgery and the exercise of ordinary care. It is appropriate to require the person against whom the signature would be asserted to make this showing. Also, in asserting a signature under this section the Bureau of the Public Debt will have to establish that it exercised ordinary care in relying upon the signature. The evidence needed to establish that it used ordinary care will be within the control of the Bureau of the Public Debt and so it is fair to require the Bureau of the Public Debt to make this showing.

In its comment letter, the Federal Reserve Board expressed concern that this section might be used to avoid the limitations of Regulation Z. As alluded to above, Regulation Z caps cardholder liability for unauthorized credit card use at $50. This section does not seek to encroach upon Regulation Z. To the extent this section might apply to unauthorized savings bond purchases involving credit cards, Treasury would be seeking to recover on a savings bond contract, not a credit card debt. In any event, Treasury has amended section 370.0 of this part to emphasize that to the extent Regulation Z applies to transactions accomplished pursuant to this part, the consumer protections extended by Regulation Z are unaffected.

(19) Liability (§ 370.57)

This section limits the Bureau of the Public Debt's liability for claims involving this subpart E to the amount

of the transaction, less any losses caused by the failure of a claimant to exercise due diligence. For instance, this section could have application to claims involving errors in the handling of otherwise properly authorized transactions.

III. Procedural Requirements

This final rule does not meet the criteria for a ''significant regulatory action,'' as defined in Executive Order 12866. Therefore, the regulatory review procedures contained therein do not apply.

This final rule relates to matters of public contract and procedures for United States securities. The notice and public procedures requirements of the Administrative Procedure Act are inapplicable, pursuant to 5 U.S.C. 553(a)(2).

As no notice of proposed rulemaking is required, the Regulatory Flexibility Act (5 U.S.C. 601, *et seq.*) does not apply.

There are no new collections of information contained in this final rule. Therefore, the Paperwork Reduction Act (44 U.S.C. 3507) does not apply.

List of Subjects in 31 CFR Parts 317, 351, 353, and 370

Bonds, Electronic Funds Transfers, Government Securities.

For the reasons set forth in the preamble, 31 CFR parts 317, 351, 353, and 370 are amended as follows:

PART 317—REGULATIONS GOVERNING AGENCIES FOR ISSUE OF UNITED STATES SAVINGS BONDS

1. The authority citation for part 317 is revised to read as follows:

Authority: 2 U.S.C. 901; 5 U.S.C. 301; 12 U.S.C. 391; 12 U.S.C. 1767; 31 U.S.C. 3105.

2. Revise § 317.1 to read as follows:

§ 317.1 Definitions.

(a) *Bond(s)* means Series EE United States Savings Bonds and Series I United States Savings Bonds.

(b) *Federal Reserve Bank* refers to the Federal Reserve Bank or Branch providing savings bond services to the district in which the issuing agent or the applicant organization is located. See § 317.9(a).

(c) *Issuing agent* refers to an organization that has been qualified by a designated Federal Reserve Bank or the Commissioner of the Bureau of the Public Debt to sell savings bonds. An issuing agent acts as an agent of the purchaser in handling the remittance. The definition encompasses:

(1) Each organization that accepts and processes purchase orders for bonds sold over-the-counter, but does not inscribe bonds, and

(2) Each organization that is authorized to inscribe bonds sold over-the-counter or through payroll savings plans.

(d) *Offering circular* refers to Department of the Treasury Circular, Public Debt Series No. 1–80, current revision, for Series EE savings bonds, and to Department of the Treasury Circular, Public Debt Series No. 1–98 for Series I savings bonds.

(e) *Organization* means an entity, as described in § 317.2, that may qualify as an issuing agent of bonds.

3. Revise § 317.2 to read as follows:

§ 317.2 Organizations authorized to act.

Organizations eligible to apply for qualification and serve as issuing agents are the following:

(a) Banks, Federal credit unions in good standing, trust companies, and savings institutions chartered by or incorporated under the laws of the United States, or those of any State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(b) Agencies of the United States and State and local governments.

(c) Employers operating payroll savings plans for the purchase of United States Savings Bonds, as well as organizations operating payroll savings plans on behalf of employers.

(d) Other organizations specifically and individually qualified by the Commissioner of the Bureau of the Public Debt whenever the Commissioner deems such a qualification to be in the public interest. In selecting an issuing agent, the Commissioner may use such process that the Commissioner deems to be appropriate. The selected issuing agent will be subject to such conditions that the Commissioner deems to be appropriate.

§ 317.3 [Amended]

4. Amend § 317.3 as follows:

A. Revise the introductory text to paragraph (a) to read as follows:

§ 317.3 Procedure for qualifying and serving as issuing agent.

(a) *Execution of application agreement.* An organization seeking issuing agent qualification generally shall obtain from and file with a designated Federal Reserve Bank an application-agreement form. However, if an organization seeks qualification under § 317.2(d) or because of its status as an organization operating a payroll savings plan on behalf of an employer under § 317.2(c), it shall make application directly to the Bureau of the Public Debt for approval by the Commissioner of the Bureau of the Public Debt. An application-agreement sent directly to the Bureau of the Public Debt shall be supplemented by such other information as the Bureau of the Public Debt may request.

* * * * *

B. Add the words ''or the Bureau of the Public Debt'' after the words ''Federal Reserve Bank'' in paragraphs (b) and (c).

5. Revise § 317.6(b) to read as follows:

§ 317.6 Issuance of bonds.

* * * * *

(b) *Fees.* Each issuing agent, other than a Federal agency, will be paid fees. Only issuing agents are eligible to collect fees. With prior approval, agents that are authorized to inscribe bonds and receive fee payments will also be paid a bonus for presorting savings bond mailings. Schedules reflecting the amount of the fees and presort bonuses, and the basis on which they are computed and paid, will be published separately in the **Federal Register**.

* * * * *

6. Amend the appendix to § 317.8 as follows:

A. Revise the section heading to the appendix to read as set out below;

B. Remove paragraph 3 of subpart B;

C. Revise paragraphs 2(c) and 2(e) of subpart A, all of subpart C, and paragraphs 2(a)(i) and 2(b) of subpart D to read as follows:

§ 317.8 Remittance of sales proceeds and registration records.

* * * * *

Appendix to § 317.8—Remittance of Sales Proceeds and Registration Records, Department of the Treasury Circular, Public Debt Series No. 4–67, Third Revision (31 CFR Part 317), Fiscal Service, Bureau of the Public Debt

Subpart A—General Information

* * * * *

2. *Definition of terms.* As used in this appendix:

* * * * *

(c) *Over-the-counter sale* means any sale of savings bonds other than payroll sales.

* * * * *

(e) *Issuing agent,* as provided in § 317.1(c) of the Circular, refers to an organization that has been qualified by a designated Federal Reserve Bank or the Commissioner of the Bureau of the Public Debt to sell savings bonds.

* * * * *

Subpart C—Remittance of Payroll Sales Proceeds

1. *Application of requirements.* The remittance requirements for payroll sales apply only to issuing agents. An employer that maintains a payroll savings plan but does not issue bonds shall be notified by the servicing issuing agent that it must remit sales proceeds to the issuing agent in sufficient time to permit compliance with the requirements.

2. *Remittance of payroll sales deductions.* Issuing agents shall remit sales proceeds throughout the month shown in the issue date as soon as the full amount of the purchase price of the bonds has been received or accumulated. In no case should such proceeds be remitted later than the second business day of the month following the month shown in the issue date. The issuing agent shall ensure that its system properly accounts for and recognizes when the full purchase price has been received, or has been accumulated, so that timely remittance can be made. The issuing agent shall transmit registration records in an electronically processible format within thirty (30) days following the month shown on the issue date.

Subpart D—Interest on Late Remittances

* * * * *

2. * * *

(a) *Bonds inscribed by issuing agent*—(i) *Payroll sales.* If, during any three (3) month period, the interest assessed on an issuing agent's late remittance of proceeds from payroll savings plan sales or thrift, savings, vacation, or similar plan sales accumulates to less than $50 for each type of sales, the interest assessed for the first month will be waived. The interest assessed for each type of sales for the remaining two (2) months will then be carried forward to the next period of three (3) consecutive months.

* * * * *

(b) *Bonds inscribed by the designated Federal Reserve Bank.* The interest assessed on late remittance of all sales proceeds transmitted during a given month will be waived if it is less than $25.

* * * * *

PART 351—OFFERING OF UNITED STATES SAVINGS BONDS, SERIES EE

1. The authority citation for part 351 continues to read as follows:

Authority: 5 U.S.C. 301; 12 U.S.C. 391; 31 U.S.C. 3105.

2. Revise § 351.1 to read as follows:

§ 351.1 Governing regulations.

Series EE bonds are subject to the regulations of the Department of the Treasury, now or hereafter prescribed, governing United States Savings Bonds of Series EE and HH, contained in Department of the Treasury Circular, Public Debt Series No. 3–80 (part 353 of this chapter). Treasury expressly disclaims the effect of, and does not warranty the correctness of, any representations or warranties regarding Series EE bonds, wherever made, that in any way conflict with the terms and conditions of Series EE bonds, as set out in these and other regulations and other applicable law. The regulations in part 370 of this chapter apply to transactions for the purchase of United States Savings Bonds issued through the Bureau of the Public Debt. The regulations in part 370 do not apply to transactions for the purchase of bonds accomplished through issuing agents generally, unless and to the extent otherwise directed by the Commissioner of the Bureau of the Public Debt.

3. Revise § 351.5 to read as follows:

§ 351.5 Purchase of bonds.

(a) *Payroll sales*—(1) *Payroll savings plans.* Bonds in $100 and higher denominations may be purchased through deductions from the pay of employees of organizations that maintain payroll savings plans. The bonds must be issued by an authorized issuing agent.

(2) *Employee thrift, savings, vacation, and similar plans.* Bonds registered in the names of trustees of employee plans may be purchased in book-entry form in $100 multiples through a designated Federal Reserve Bank after Bureau of the Public Debt approval of the plan as eligible for the special limitation under § 353.13 of this chapter, also published as § 353.13 of Department of the Treasury Circular, Public Debt Series No. 3–80.

(b) *Over-the-counter sales*—(1) *Eligible issuing agents.* Bonds may be purchased through any issuing agent, except that an organization serving as an issuing agent because of its status as an employer or an organization operating an employer's payroll savings plan under § 317.2(c) of this chapter may sell bonds only through payroll savings plans.

(2) *Manner of sale.* An application for the purchase of a bond must be accompanied by a remittance to cover the issue price. The purchase application and remittance may be submitted to an issuing agent by any means acceptable to the issuing agent. An application may authorize purchases on a recurring basis. The issuing agent bears the burden of collection and the risk of loss for non-collection or return of the remittance.

PART 353—REGULATIONS GOVERNING UNITED STATES SAVINGS BONDS, SERIES EE AND HH

1. The authority citation for part 353 is revised to read as follows:

Authority: 5 U.S.C. 301; 12 U.S.C. 391; 31 U.S.C. 3105, 3125.

§ 353.6 [Amended]

2. Remove the word ''deduction'' in § 353.6(b)(4), and add, in its place, the word ''savings.''

§ 353.13 [Amended]

3. Add the phrase '', as amended'' after the word ''1954'' in § 353.13(c)(3).

4. Revise paragraph (a) of § 353.21 to read as follows:

§ 353.21 Payment to judgment creditors.

(a) *Purchaser or officer under levy.* The Department of the Treasury will pay (but not reissue) a savings bond to the purchaser at a sale under a levy or to the officer authorized under appropriate process to levy upon property of the registered owner or coowner to satisfy a money judgment. Payment will be made only to the extent necessary to satisfy the money judgment. The amount paid is limited to the redemption value 60 days after the termination of the judicial proceedings. Except in a case of a levy by the Internal Revenue Service, payment of a bond registered in coownership form pursuant to a judgment or a levy against only one coowner is limited to the extent of that coowner's interest in the bond. That interest must be established by an agreement between the coowners by judgment, decree, or order of a court in a proceeding to which both coowners are parties. Payment of a bond registered in coownership form pursuant to levy by the Internal Revenue Service will be made if the levy is against either coowner on the bond.

5. Revise § 353.27 to read as follows:

§ 353.27 Application for relief—Non-receipt of bond.

If a bond issued on any transaction is not received, the issuing agent must be notified as promptly as possible and given all information about the non-receipt. An appropriate form and instructions will be provided. If the application is approved, relief will be granted by the issuance of a bond bearing the same issue date as the bond that was not received. Also, relief is authorized for the issuance of bonds for

which the Secretary has not received payment, in order to preserve public confidence in dealing with issuing agents.

PART 370—REGULATIONS GOVERNING ELECTRONIC TRANSACTIONS AND THE TRANSFER OF FUNDS BY ELECTRONIC MEANS ON ACCOUNT OF UNITED STATES SECURITIES

1. The authority citation for part 370 is revised to read as follows:

Authority: 12 U.S.C. 391; 31 U.S.C. chapter 31.

2. The heading of part 370 is revised to read as set forth above.

3. Revise subpart A to read as follows:

Subpart A—General Information

Sec.
370.0 Applicability.
370.1 Definitions.

Subpart A—General Information

§ 370.0 Applicability.

The regulations in this part apply to electronic transactions and the transfer of funds by electronic means as employed by the Bureau of the Public Debt in connection with United States securities, except as varied by agreement or as otherwise provided. To the extent that the regulations in part 210 of this title apply to the purchase or payment of interest and principal on United States securities, the regulations in this part 370 apply in the event of any inconsistencies. Among other things, the written authorization of the Financial Management Service is not necessary for the issuance of routing numbers by a Federal Reserve Bank or for the receipt, origination, or reversal of any credit or debit entry accomplished pursuant to this part. Finally, to the extent that Regulation E (12 CFR part 205) and Regulation Z (12 CFR part 226) of the Board of Governors of the Federal Reserve System may apply to transactions authorized by this part, those Federal laws are unaffected by this part.

§ 370.1 Definitions.

Automated Clearing House (ACH) entry means a transaction in accordance with applicable Operating Rules and Operating Guidelines of the National Automated Clearing House Association, as modified by these and other regulations and law. The regulations in this part control in the event of any inconsistencies with the applicable Operating Rules and Operating Guidelines.

Credit entry means an ACH entry for the deposit of money to a deposit account.

Debit entry means an ACH entry for the payment of money from a deposit account.

Deposit account means a demand deposit (checking), savings, or asset account (other than an occasional or incidental credit balance in a credit plan) held directly or indirectly by a financial institution.

Digital signature means a type of electronic signature. A digital signature uses public-key encryption and a message digest function to transform an electronic record. A person who has the initial electronic record and the signer's public key can verify:

(1) Whether the transformation was accomplished by the private key that corresponds to the signer's public key; and

(2) Whether the initial record has been altered since the transformation was made.

Electronic signature means a signature manifested through electronic or similar means, including digital and biometric methods.

Financial institution means:

(1) An entity described in section 19(b)(1)(A), excluding subparagraphs (v) and (vii), of the Federal Reserve Act (12 U.S.C. 461(b)(1)(A)). Under section 19(b)(1)(A) of the Federal Reserve Act and for purposes of this part only, the term ''depository institution'' means:

(i) Any insured bank as defined in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813) or any bank that is eligible to make application to become an insured bank under section 5 of such Act (12 U.S.C. 1815);

(ii) Any mutual savings bank as defined in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813) or any bank that is eligible to make application to become an insured bank under section 5 of such Act (12 U.S.C. 1815);

(iii) Any savings bank as defined in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813) or any bank that is eligible to make application to become an insured bank under section 5 of such Act (12 U.S.C. 1815);

(iv) Any insured credit union as defined in section 101 of the Federal Credit Union Act (12 U.S.C. 1752) or any credit union that is eligible to make application to become an insured credit union pursuant to section 201 of such Act (12 U.S.C. 1781);

(v) Any savings association as defined in section 3 of the Federal Deposit Insurance Act (12 U.S.C. 1813) that is an insured depository institution (as defined in such Act) (12 U.S.C. 1811 *et seq.*) or is eligible to apply to become an insured depository institution under the Federal Deposit Insurance Act (12 U.S.C. 1811 *et seq.*); and

(2) Any agency or branch of a foreign bank as defined in section 1(b) of the International Banking Act, as amended (12 U.S.C. 3101).

Message digest function means an algorithm mapping or translating one sequence of bits into another, generally smaller, set such that:

(1) An electronic record yields the same message digest result every time the algorithm is executed using the same electronic record as input;

(2) It is computationally infeasible that an electronic record can be derived or reconstituted from the message digest result produced by the algorithm; and

(3) It is computationally infeasible that two electronic records can be found that produce the same message digest using the algorithm.

Originator means an entity authorized by a person to initiate debit or credit entries to the person's deposit account and that also has an agreement with a financial institution to transmit the debit or credit entries to the person's deposit account.

Owner means the person(s) in whose name(s) a security is registered.

Payment means, for the purpose of subpart B of this chapter, the deposit of money from the Department of the Treasury to the deposit account of the owner.

Person means any natural person or organization.

Public-key encryption means a process which generates and employs a key pair consisting of a private key and its mathematically related public key, in which one use of the public key is to verify a digital signature created by the private key.

Record means information that is inscribed on a tangible medium or that is stored in an electronic or other medium and is retrievable in perceivable form.

Security means any obligation issued by the United States that, by the terms of the applicable offering circular, is made subject to this part.

Settlement date means the date an exchange of funds with respect to an entry is reflected on the books of the Federal Reserve Bank(s). For a security held in the TREASURY DIRECT system, the issue date will in most cases be the same as the settlement date. For United States Savings Bonds, the issue date will in most cases be the first day of the month in which settlement takes place.

Signature means any symbol or method executed or adopted by a party with present intention to be bound.

4. Revise the heading of subpart C to read as follows:

Subpart C—Debit ACH Entries for the Sale of Securities in TREASURY DIRECT

* * * * *

Subpart D—Redesignated

5. Redesignate subpart D as subpart F and §§ 370.30 and 370.31 as §§ 370.60 and 370.61.

6. Add subparts D and E to read as follows:

Subpart D—Debit ACH Entries for the Sale of United States Savings Bonds Issued Through the Bureau of the Public Debt

Sec.

Subpart O—Debit ACH Entries for the Sale of United States Savings Bonds Issued Through the Bureau of the Public Debt

§ 370.30 Scope.

This subpart provides regulations for Automated Clearing House debit entries used for the sale of United States Savings Bonds issued through the Bureau of the Public Debt. This subpart also establishes the exclusive liability of the Bureau of the Public Debt for such entries. This subpart does not apply to transactions for the sale of United States Savings Bonds accomplished through savings bond issuing agents generally, unless and to the extent the Commissioner of the Bureau of the Public Debt directs otherwise.

§ 370.31 Authorization.

(a) *General.* The purchaser of a security shall authorize an originator to initiate Automated Clearing House debit entries and shall designate a deposit account at a financial institution to receive such entries. An authorization shall be accomplished only through a form approved by the Bureau of the Public Debt.

(b) *Persons to sign.* The signatures of the purchaser and any other persons whose signatures ordinarily are required to withdraw funds from the designated deposit account are necessary for the authorization to be effective. Except to the extent required by the Bureau of the Public Debt, the originator will not be required to verify the identity of the purchaser or the authenticity of the signatures.

(c) *Recurring debit entries.* A single authorization may allow or require debit entries to be made to a deposit account on a recurring basis, if the approved authorization form so provides.

(d) *Subsequent authorizations.* A purchaser's subsequent authorization cancels a previous authorization.

(e) *Successor originator.* The Bureau of the Public Debt reserves the right to name a successor to the originator named on the debit authorization form. The designation of a successor shall be effective without additional notice to the purchaser.

§ 370.32 Prenotification.

The requirement of a prenotification prior to the initiation of any debit entry is left to the discretion of the Bureau of the Public Debt. If sent, the receiving financial institution must respond within the time frame for such responses established by the National Automated Clearing House Association. If a prenotification is sent and the receiving financial institution does not reject or otherwise respond to the prenotification message within the specified time period, the financial institution shall be deemed to have warranted to Treasury and the originator that the information as to the deposit account number and the type of account contained in the message is accurate as of the time of receipt of the prenotification.

§ 370.33 Warranties of financial institution.

A financial institution's acceptance and handling of a debit entry or failure to timely reject a prenotification made with respect to a security covered by this subpart shall constitute its agreement to the provisions of this subpart. In addition to warranties referred to in § 370.32, a financial institution that agrees to this part also warrants that it has the authority to receive entries and to comply with any requirements imposed upon Receiving Depository Financial Institutions under the Operating Rules and Operating Guidelines of the National Automated Clearing House Association, as modified by these and other regulations and law.

§ 370.34 Responsibilities of financial institution.

A financial institution that receives a debit entry on behalf of its customer must debit the customer's account on the settlement date. If the financial institution is unable to debit the designated account, it shall return the entry by no later than the next business day after receipt, with an electronic message or other response explaining the reason for the return.

§ 370.35 Termination or suspension by the Bureau of the Public Debt.

The Bureau of the Public Debt may terminate or suspend the availability of debit entries as a means of purchase for savings bonds at any time. A decision to terminate or suspend the availability of debit entries as a means of purchase is in the sole discretion of the Bureau of the Public Debt and shall be final.

§ 370.36 Termination or suspension by purchaser or deposit account owner by notice to the originator.

A purchaser of a security or a deposit account owner may terminate or suspend debits by notifying the originator orally or in writing at least three business days before the scheduled date of the transfer. In response to an oral notice, the originator may require the consumer to give written notice, to be received by the originator within 14 days of an oral notice. An oral notice ceases to be binding after 14 days if the purchaser fails to provide the required written confirmation. A suspension will remain in effect for the duration specified by the purchaser, but for no more than six months. The termination and revocation methods need not be recited in the authorization.

§ 370.37 Changes and error resolution.

While responding to an oral or written notice from a person relating to the propriety of security issuance information or a debit entry involving the person's deposit account, the originator may suspend further debit entries. In response to an oral notice, the originator may require the person to give written notice, to be received by the originator within 10 business days of an oral notice. The originator promptly will investigate the allegation and provide relief for any error, but is not bound to complete the investigation or correct the error within 10 business days if the requested written confirmation is not provided.

§ 370.38 Liability.

(a) *Scope of liability.* Unless the Bureau of the Public Debt has designated itself or a fiscal or financial agent as an originator, the Bureau of the Public Debt shall not be liable for any unauthorized, erroneous, duplicative, or otherwise improper debit entries, and shall not be liable for a failure to debit a deposit account. Unless the Bureau of the Public Debt has designated itself or

a fiscal or financial agent as the originator, the originator serves as the agent of the purchaser in handling the remittance. Any claims must be pursued against the originator. The Bureau of the Public Debt shall not be liable for its choice of an originator. The Bureau of the Public Debt shall not be liable to any Automated Clearing House association.

(b) *Extent of liability.* For any claim involving this subpart that may proceed against the Bureau of the Public Debt, the Bureau of the Public Debt's liability is limited to the amount of the improper debit and does not extend to other damages or costs, including consequential damages, punitive damages, the costs of litigation, or payment of attorney fees. The liability of the Bureau of the Public Debt also shall be reduced by the amount of the loss resulting from a failure of the claimant to exercise due diligence, including a failure to follow standard commercial practices.

Subpart E—Electronic Submission of Transaction Requests Through the Bureau of the Public Debt

Sec.

Subpart E—Electronic Submission of Transaction Requests Through the Bureau of the Public Debt

§ 370.50 Scope.

This subpart provides general regulations for the electronic submission of transaction requests through the Bureau of the Public Debt. This subpart also establishes the exclusive liability of the Bureau of the Public Debt for transactions accomplished under this subpart. This subpart does not apply to transactions for the sale of United States Savings Bonds accomplished through savings bond issuing agents generally, unless and to the extent the Commissioner of the Bureau of the Public Debt directs otherwise.

§ 370.51 Requirements.

An electronically signed transaction request cannot be accepted by the Bureau of the Public Debt unless the signature has been accomplished through a method that has been approved for specific purposes by the Bureau of the Public Debt.

§ 370.52 Time of acceptance.

A transaction request submitted electronically, including an offer to purchase a security, is accepted no earlier than at the moment the request is received by the Bureau of the Public Debt and no later than at the moment a message of acceptance is sent by the Bureau of the Public Debt, regardless of the method used to transmit the message of acceptance.

§ 370.53 Point of transaction.

For jurisdiction and venue purposes, the point of transaction for a transaction request handled pursuant to this subpart is Parkersburg, West Virginia, regardless of from where the transaction request is transmitted or where the transaction request is actually processed.

§ 370.54 Effect of electronic signature.

An electronic signature and any electronic record to which it is affixed or attached may not be denied legal effect, including legal effect as a signature, a writing, or an original, solely because the signature or record is in electronic form.

§ 370.55 Admissibility of digital signature.

The requirement of authentication or identification as a condition precedent to admissibility is satisfied by evidence sufficient to support a finding that a digital signature exists. However, in asserting a digital signature against a particular person in any civil litigation or dispute, extrinsic evidence of authenticity as a condition precedent of admissibility shall not be necessary to establish that a digital signature corresponds to a specific public key pair and that an electronic record to which the digital signature is affixed has not been altered from its original form.

§ 370.56 Negligence contributing to forged signature.

A person whose failure to exercise ordinary care substantially contributes to the creation or submission of a forged signature is precluded from disavowing the forged signature. The burden of production and the burden of persuasion is on the person against whom the signature is asserted to establish the exercise of ordinary care. However, in asserting a signature under this section, the Bureau of the Public Debt bears the burden of production and the burden of persuasion in establishing that it exercised ordinary care in relying upon the signature.

§ 370.57 Liability.

For any claim involving this subpart that may proceed against the Bureau of the Public Debt, the Bureau of the Public Debt's liability is limited to the amount of the transaction and does not extend to other damages or costs, including consequential damages, punitive damages, the costs of litigation, or payment of attorney fees. The liability of the Bureau of the Public Debt shall also be reduced by the amount of the loss resulting from a failure of the claimant to exercise due diligence, including a failure to follow standard commercial practices.

Dated: November 10, 1998.

Donald V. Hammond,

Fiscal Assistant Secretary.

[FR Doc. 98–31089 Filed 11–19–98; 8:45 am]

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Friday
November 20, 1998

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16 and 99

Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 99

[Docket No. 98N–0222]

RIN 0910–AB23

Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations pertaining to the dissemination of information on unapproved uses (also referred to as ''new uses'' and ''off-label uses'') for marketed drugs, including biologics, and devices. The final rule describes the new use information that a manufacturer may disseminate and describes the content of and establishes procedures for a manufacturer's submission to FDA before it may begin disseminating information on the new use. The final rule also describes how manufacturers seeking to disseminate information on a new use must agree to submit a supplemental application for that use within a specified period of time, unless a supplemental application already has been submitted or FDA has exempted the manufacturer from the requirement to submit a supplement. The final rule provides for requests to extend the time period for submitting a supplemental application for a new use and describes how a manufacturer can seek an exemption from the requirement to submit a supplemental application for the new use. Additionally, the final rule discusses FDA actions in response to manufacturers' submissions, corrective actions that FDA may take or require, and recordkeeping and reporting requirements. The final rule implements sections 551 through 557 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aaa through 360aaa-6) as amended by section 401 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: The final rule is effective November 20, 1998. Written comments on the information collection requirements should be submitted by January 19, 1999.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding biological products and devices regulated by the Center for Biologics Evaluation and Research: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM–602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–3028;

Regarding human drug products: Laurie B. Burke, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828;

Regarding medical devices: Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of June 8, 1998 (63 FR 31143), FDA published a proposed rule that would add to title 21 of the Code of Federal Regulations (CFR) a new part 99 entitled, ''Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices.''

The proposed rule was intended to implement section 401 of FDAMA. In brief, section 401 of FDAMA amended the act to permit drug, biologic, and device manufacturers to disseminate certain written information concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and Federal and State Government agencies, provided that the manufacturer complies with certain statutory requirements. For example, the information that is to be disseminated must be about a drug or device that is being legally marketed; it must be in the form of an unabridged reprint or copy of a peer-reviewed journal article or reference publication; and it must not be derived from another manufacturer's clinical research, unless that other manufacturer has given its permission for the dissemination. The information must be accompanied by certain information, including a prominently displayed statement that the information discusses a use or uses that have not been approved or cleared by FDA. Additionally, 60 days prior to the dissemination, the manufacturer must submit to FDA a copy of the information to be disseminated and any other clinical trial information that the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience that pertain to the safety of the new use, and a summary of such information.

A detailed description of section 401 of FDAMA appeared in the preamble to the proposed rule (see 63 FR 31143 at 31144 and 31145).

II. Highlights of the Final Rule

Although the statute is very detailed, and the final rule closely tracks its provisions, there are some places where the regulation fills in the details of the statutory requirements. For example, the final rule defines terms that were not defined in the legislation (e.g., ''supplemental application'' and ''clinical investigation,'' and it explains concepts that required additional explanation (e.g., what is meant by the term ''unabridged''). The final rule also sets forth the more detailed procedures for how to submit the required information to FDA before disseminating any new use information (e.g., where the information should be submitted and how many copies are required). Finally, the final rule defines what is meant by the basic criteria that the statute sets forth for granting an exemption from the requirement to submit a supplement application on the basis that it would be unethical or economically prohibitive to conduct the studies needed to submit a supplemental application.

The final rule has been revised in response to comments received on the proposal. For example, § 99.3 was revised to add a definition for pharmacy benefit manger, which is not included in the statute. The definition of ''clinical investigation'' in § 99.3 also was revised. Section 99.101 was revised to reflect FDA's position that most journal articles and reference texts (as those terms are defined in the regulation) would be considered to be scientifically sound and to describe specific instances (e.g., letters to the editor, Phase 1 trials in healthy individuals) when that would not be the case.

Section 99.103 revised the mandatory statement that the disseminated information has not been approved or cleared by FDA. That section also was revised to ensure that the financial disclosures required under this part would be consistent with FDA's final rule on financial disclosures by clinical investigators.

Sections 99.201(a)(4)(i)(B) and (a)(4)(ii)(B), 99.203(b), and 99.401(b) were revised to clarify that for purposes of computing time periods that begin on the date of initial dissemination, FDA will look to the date that dissemination can begin. This clarification was

necessary because FDA will not know when a manufacturer actually begins to disseminate materials.

Sections 99.203 and 99.303 were revised to clarify that there are two different ways that FDA can extend the time period for completing the studies needed to submit a supplemental application for a new use: One before any studies have begun and one after the studies have begun. FDA also revised the standard for granting an exemption from the requirement to submit a supplemental application on the basis that it would be economically prohibitive. The focus is now on the revenue from the new use rather than the revenue from the product.

In § 99.301, FDA clarified when it would require a manufacturer to keep records identifying the individual recipients of new use information as opposed to just the categories of such recipients. Finally, the final rule was revised to ensure that a decision on a new use submission would be made within 60 days.

III. Responses to Comments on the Proposed Rule

FDA received over 50 written comments on the proposed rule. In addition, on July 8, 1998, FDA held a public meeting on the proposed rule. Thirteen speakers commented on the proposal. In general, the comments expressed a diverse range of opinions, both favoring and opposing the proposed rule, and were submitted by health professionals, medical organizations, consumer groups, patient groups, a medical journal, members of Congress, trade associations, and manufacturers.

A. General Comments

Several comments addressed the concept of disseminating information on unapproved or new uses rather than the proposed rule itself. Other comments sought further restrictions on the dissemination of information on unapproved or new uses, while still other comments sought to expand the rule to cover more products.

1. A number of comments expressed concern that the proposed rule could result in harm to patients. One comment expressed concern over the self-policing aspects of the rule. Another comment cited several examples where drugs were administered for unapproved uses and proved to be harmful. The comment stated that dissemination of information on unapproved uses for approved drugs would further encourage the use of ''untested'' drugs and discourage clinical trials that would show whether the drugs are safe and effective for their intended uses. The comment asked FDA to ''revise or abandon these regulations so as to continue to protect consumers from untested and potentially dangerous drugs.'' One comment argued that the new rule was not ''warranted'' because the disseminated information may be inappropriate and would pose a significant risk to public health. The comment further argued that current practices in this area are the best way to handle information on unapproved uses. Finally, a number of comments expressed concern that FDA does not have sufficient resources to implement the regulation in a manner that can adequately protect the public health. Such comments urged FDA to direct adequate resources to implementation.

Section 401(c) of FDAMA required FDA to issue regulations to implement sections 551 through 557 of the act by November 21, 1998. The final rule, which closely tracks the statutory language, represents FDA's effort to comply with that requirement. FDA is committed to implementing this new statutory authority consistent with its obligation to protect the public health.

2. Several comments claimed that dissemination of information on unapproved or new uses of drugs for which pediatric labeling is not available would be contrary to section 505A of the act (21 U.S.C. 355A) as it pertains to pediatric studies of drugs because it would impede the development of pediatric data. Several comments said that dissemination of information on unapproved uses for pediatric therapy should be limited to drugs that have ''sufficient labeling in the ages of the children addressed by the information disseminated.'' Another comment noted that dissemination of information for an unapproved use of a drug in children when the drug's approved use has not been tested for safety in pediatric patients may pose even more risk than unapproved uses generally. Others said that for drugs without labeling for pediatric populations or specific age populations, drug manufacturers should not be able to disseminate unapproved use information about pediatric populations or about specific age populations not specified in the label, unless such information is specifically requested by the physician.

FDA declines to amend the rule as suggested by the comments. It is FDA's hope that the statutory scheme set forth in section 401 of FDAMA and implemented by this part will actually stimulate research and the development of data on new uses, including pediatric uses. Moreover, nothing in section 401 of FDAMA or its legislative history suggests that Congress intended to exclude pediatric uses from section 551 of the act or to further limit how information on such uses can be disseminated. Finally, the act does not require that the disseminated information be specifically requested by a physician in order to be disseminated.

Although FDA is not amending the codified language in any way, it does recognize that the potential dangers of unapproved uses in children may be greater than for adults because few drugs have been tested in children. The agency will take this into account in making a determination as to whether a proposed dissemination of information on a new use poses a significant risk to public health such that the dissemination under this part should not be permitted.

3. One comment would revise the rule to exclude drugs that may be covered by orphan drug exclusivity. The comment explained that a manufacturer may obtain orphan drug exclusivity for a particular use of a drug, but that other manufacturers could be marketing the same drug for non-orphan indications. The comment stated that such other manufacturers could disseminate information on the orphan indication, thereby undermining the value of orphan drug exclusivity.

There is no indication in section 401 of FDAMA or its legislative history that Congress intended the dissemination of information on unapproved uses of drugs and devices to undermine patent protection or exclusivity granted to a product under the Orphan Drug Act, the Waxman-Hatch Amendments, or the pediatric exclusivity provisions in section 111 of FDAMA. Therefore, an indication that is not included in a particular sponsor's approved product labeling because the indication is protected by patent or exclusivity is not eligible for dissemination under part 99.

4. Several comments urged FDA to broaden the proposal to include over-the-counter (OTC) drug products being marketed under an OTC monograph.

Section 401 of FDAMA requires that in the case of a drug, there be in effect for the drug an application filed under section 505(b) or (j) of the act. OTC drugs being marketed under an OTC monograph do not have an application filed under section 505(b) or (j) of the act in effect. Therefore, FDA declines to revise the rule as suggested in these comments.

5. One comment stated that companies sometimes assist physicians and patients in obtaining reimbursement from Medicare, Medicaid, and private insurers by furnishing copies of journal articles and reference publications on unapproved

uses to the insurer or government agency when reimbursement is denied on the ground that use of the product is experimental. The comment concluded that this practice appeared to be legal prior to the passage of section 401 of FDAMA and asked FDA to clarify that it did not become illegal as a result of FDAMA.

Prior to passage of FDAMA, the practice described in this comment was not permissible unless the unapproved use information was provided in response to an unsolicited request for such information. FDA's policy, which allows manufacturers to provide unapproved use information in response to an unsolicited request, was not affected by FDAMA (see section 557(a) of the act). Accordingly, manufacturers who wish to furnish unapproved use information as described in the comment may do so if it is in response to an unsolicited request. Otherwise, they must comply with the requirements set forth in section 401 of FDAMA and this part.

6. One comment asserted that the proposal should recognize the specific legal authorization for manufacturers to provide off-label information to health care practitioners in response to an unsolicited request.

Section 401 of FDAMA added a new section 557(a) of the act, which provides that nothing in section 551 of the act shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner. Although FDA does not construe section 557(a) of the act as a specific legal authorization for manufacturers to provide off-label use information to health care practitioners in response to an unsolicited request, § 99.1(b) of the final rule recognizes this statutory provision.

7. One comment stated that FDA should exempt manufacturers from the ''pre-approval and reporting requirements'' when the primary focus of a publication is on the approved uses of the product.

Section 401 of FDAMA and this part do not cover publications regarding approved uses. FDA intends to permit manufacturers to disseminate certain information that focuses primarily on approved uses and that report the results of studies that have been relied on by FDA in its approval or clearance of a drug or device without meeting all of the requirements set forth in this part. (Cf. Guidance to Industry on Dissemination of Reprints of Certain Published Original Data (61 FR 52800, October 8, 1996). The agency was enjoined from applying this guidance document in *Washington Legal Foundation* v. *Friedman*, CA No. 1:94CV1306 (D.D.C. July 30, 1998) (hereinafter referred to as *WLF* v. *Friedman*). FDA sought clarification on the scope of the order through a motion to amend the judgment in that case.) FDA plans to issue guidance on this issue at some time in the future pending clarification by the court.

8. One comment suggested that FDA exempt manufacturers from the requirements set forth in this part if the new use that is the subject of the information being disseminated has been accepted as standard medical practice (i.e., indications listed in the United States Pharmacopoeia Drug Information for the Health Care Professional (USP DI) or American Hospital Formulary Service, etc.).

FDA declines to create an exemption from the entire rule as suggested by the comment. Regardless of whether the unapproved use is listed in the USP DI or American Hospital Formulary Service, the statutory requirements in sections 551 through 557 of the act apply to a manufacturer who intends to disseminate information on the unapproved use for an approved product to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or Federal or State governmental agencies. Evidence that the unapproved use represents standard medical care may, however, enable the manufacturer to seek an exemption from the requirement to submit a supplemental application for the unapproved use if the manufacturer can demonstrate that it would be unethical to conduct the studies necessary for a supplemental application for the new use. A discussion of the ''unethical'' exemption appears later in section III of this document.

9. Some comments stated that the proposal properly reflects the intent of Congress and achieves the important goals of assuring the public health and encouraging the dissemination of information. Others argued that the proposal is contrary to congressional intent, paternalistic and cumbersome, and would restrict, rather than facilitate, access to information about new uses.

Although FDA drafted the proposed rule to reflect congressional intent, the agency has revised the rule in response to specific comments. These revisions are meant to ensure that the final rule more accurately reflects congressional intent.

B. Comments on Specific Provisions

1. Subpart A—General Information

a. Scope (§ 99.1). Proposed § 99.1 described the scope of part 99, explaining that the part applies to the dissemination of information on human drugs, including biologics, and devices where the information to be disseminated pertains to the safety, effectiveness, or benefit of a use that is not included in the approved labeling for an approved drug or device or in the statement of intended use for a cleared device and the information is to be disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency.

10. Several comments urged FDA to add pharmacists to the list of recipients of information under this part.

Section 401 of FDAMA specifically lists who can receive the new use information under this provision and proposed § 99.1 tracked that statutory provision. Therefore, FDA declines to amend the regulation as requested. However, to the extent that pharmacists fall within the definitions of ''health care practitioner,'' ''pharmacy benefit manager,'' health insurance issuer,'' or ''group health plan'' (see § 99.3) they will be included as recipients of this information.

b. Definitions (§ 99.3). Proposed § 99.3 defined various terms, such as ''clinical investigation'' (proposed § 99.3(b)), ''health care practitioner'' (proposed § 99.3(d)), ''new use'' (proposed § 99.3(g)), ''scientific or medical journal'' (proposed § 99.3(i)), and supplemental application (proposed § 99.3(j)).

11. One comment urged FDA to include a definition for ''pharmacy benefit manager'' and to include pharmacists in that definition.

Although the statute defines the other recipients of information under this provision (i.e., health care practitioner, health insurance issuer, and group health plan), it does not define pharmacy benefit manager. FDA has revised the rule to define a ''pharmacy benefit manager'' (PBM) as ''a person or entity that has, as its principal focus, the implementation of one or more device and/or prescription drug benefit programs.'' PBM's, which generally include pharmacists, typically provide claims processing services for devices and/or prescription drugs; negotiate device and/or prescription drug prices; negotiate volume purchase agreements with medical device and/or pharmaceutical manufacturers, develop formularies, and institute formulary

compliance programs (e.g., mandatory generic substitution programs). The new definition is in § 99.3(h) and the agency has redesignated the remaining definitions accordingly.

12. Proposed § 99.3(b) defined a ''clinical investigation'' as an ''investigation in humans that is prospectively planned to test a specific clinical hypothesis.'' Several comments argued that FDA should delete the proposed definition of ''clinical investigation.'' They argued that restricting clinical investigations to those that are prospectively planned is not part of the statute, that it would preclude the use of retrospective studies, modeling studies, open label studies, metanalysis, reference articles, and consensus standards, which these comments assert may be useful, and that Congress never intended for the definition to be limited in this manner. One comment argued that the prospective planning criteria should not have to meet the criteria for investigational new drug applications (IND's).

FDA believes that many of these comments misconstrued what the agency meant by the phrase ''prospectively planned.'' FDA does not consider modeling studies, which are not actual studies, but rather extrapolations of information or data that are used to predict how a study might come out, to be clinical investigations. Moreover, FDA does not consider consensus standards and reference articles to contain adequate detail about ''clinical investigations'' as defined by this rule. However, it was the agency's intent that the definition could include historically controlled studies, retrospective analyses, open label studies, and metanalyses if they are testing a specific clinical hypothesis. To avoid any confusion, FDA is eliminating the phrase ''prospectively planned'' from the definition of ''clinical investigation.'' In the final rule, FDA has defined a clinical investigation to mean ''an investigation in humans that tests a specific clinical hypothesis.''

13. Several comments urged FDA to revise the definition of ''health care practitioner'' in § 99.3(d) to include pharmacists.

Section 556(1) of the act (21 U.S.C. 360aaa-5(1)) defines the term ''health care practitioner'' to mean a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs or devices.'' FDA's proposed regulation tracked this statutory definition. FDA declines to revise the definition. To the extent that pharmacists fall within this definition, they will be eligible to receive information disseminated under this part.

14. Proposed § 99.3(g) defined ''new use'' to mean a use that is not included in the approved labeling of an approved drug or device, or a use that is not included in the statement of intended use for a cleared device. The preamble to the proposed rule explained that a new use is one that would require approval or clearance of a supplemental application in order for it to be included in the product labeling.

The preamble to the proposed rule explained that ''new uses,'' include, but are not limited to: A completely different indication; modification of an existing indication to include a new dose, a new dosing schedule, a new route of administration, a different duration of usage, a new age group (e.g., unique safety or effectiveness in the elderly), another patient subgroup not explicitly identified in the current labeling, a different stage of the disease, a different intended outcome (e.g., long-term survival benefit, improved quality of life, disease amelioration), effectiveness for a sign or symptom of the disease not in the current labeling; and comparative claims to other agents for treatment of the same condition (see 63 FR 31143 at 31145).

A number of comments supported FDA's definition of new use. However, others disagreed with the specific examples set forth in the preamble as too broad. Most of the latter comments objected to the inclusion of patient subgroups and comparative claims for approved indications. They argued that their inclusion in the definition is inconsistent with the agency's prescription drug advertising regulations, which permit companies to promote patient subgroups and comparative claims if certain conditions are met. Several comments disagreed with the inclusion of a new age group—specifically children—in the definition of new use. One comment argued that children should not be considered a ''use,'' but a ''user.'' One comment stated that the definition should focus only on information that differs from the current labeling; it should not include information that is consistent with, but more detailed than what is described in the approved labeling. Finally, one comment disagreed with the agency's characterization of a different intended outcome as an off-label use.

FDA agrees with the comments discussed previously, which note that FDA's prescription drug advertising regulations permit companies to make comparative claims about two approved uses, without getting the claims on the approved label if the companies have on file, substantial evidence or substantial clinical experience to support such claims. (See § 202.1(e) (21 CFR 202.1(e)).) FDA did not intend to change the provision found in its prescription drug advertising regulations. In addition, FDA agrees that as long as the comparison is between two approved claims, there technically is not a new ''use'' involved. Therefore, FDA is deleting comparative claims about approved uses from its interpretation of ''new use.'' Manufacturers who want to make such claims for a drug, must submit a labeling supplement or must meet the requirements set forth in FDA's drug advertising regulations. (See § 202.1(e).) Manufacturers who want to make such claims for a medical device must meet the requirements set forth in §§ 807.81(a)(3)(ii) or 814.39 (21 CFR 807.81(a)(3)(ii) or 814.39).

With respect to claims of efficacy in a new patient subgroup, including a new age group, claims that are more detailed than the approved labeling, and claims that relate to different intended outcomes (as well as with respect to some of the other types of new use claims listed in the preamble to the proposed rule), FDA's prescription drug advertising regulations may permit companies to make such claims about prescription drugs in certain circumstances, without submitting a supplement, provided they have on file the required evidence to support the claim. (See § 202.1(e).) However, FDA does consider such claims, including claims regarding children, to be new uses in some cases. In cases where such claims constitute new uses, manufacturers also can use the procedures set forth in this part to disseminate journal articles and reference publications about those claims. For medical devices, manufacturers can use the procedures set forth in this part to disseminate journal articles and reference publications about these types of claims. Otherwise, they must comply with the requirements set forth in §§ 807.81(a)(3)(ii) or 814.39.

15. Proposed § 99.3(i) (now redesignated as § 99.3(j)) defined ''scientific or medical journal,'' in part, as a journal that is indexed in Index Medicus. It excluded scientific and medical publications that are in the form of special supplements that have been funded in whole or in part by one or more manufacturers. One comment agreed that special supplements are not appropriate for dissemination under this part. One comment, however, stated that the definition was too narrow by requiring that the publication be listed

in Index Medicus and by excluding special supplements.

The definition in FDA's rule, which excludes journals not indexed in Index Medicus and scientific and medical publications that are in the form of special supplements that have been funded in whole or in part by one or more manufacturers, tracks the statutory definition. (See section 556(5) of the act.) Accordingly, no changes to the final rule have been made.

16. Proposed § 99.3(j) (now redesignated as § 99.3(k)) defined ''supplemental application'' as a supplement to support a new use to an approved new drug application (NDA) for human drugs or a supplement to an approved license application for biologics. Several comments argued that the definition of a supplemental application for a drug should be expanded to include the possibility that a ''new use'' could require a new NDA rather than just a supplemental NDA. One comment claimed that there are certain review divisions in the Center for Drug Evaluation and Research (CDER) that require NDA's for all new uses.

There may be times when a manufacturer would be required to submit an NDA rather than a supplemental NDA to support a new use. In these instances, the unapproved use would not be covered by this part. However, it would not be appropriate to exclude new uses from this part merely because a review division assigns a new NDA number to the supplement for administrative convenience. In the latter instance, the difference would be in name only. Therefore, although FDA is declining to revise the regulation as suggested by the comments, FDA will treat applications that have been assigned a new NDA number for administrative convenience as a supplemental NDA for purposes of this part.

17. One comment recommended expanding the definition of supplemental application to cover OTC drugs that are subject to a monograph.

As set forth previously, OTC drugs that are subject to a monograph are not covered by this provision. Therefore, FDA declines to expand the definition as requested.

18. For devices, proposed § 99.3(j) (now redesignated as § 99.3(k)) defined ''supplemental application'' as a new 510(k) submission, if the device that is cleared for marketing is the subject of a 510(k) submission, or a supplement to an approved premarket approval application (PMA), if the device that is marketed is the subject of an approved PMA. One comment recommended expanding the definition of supplemental application for devices to include a 510(k) to a 510(k) exempt device.

FDA agrees that the statutory provision covers 510(k) exempt devices and so has amended the definition of supplemental application accordingly.

19. Several comments disagreed with FDA's definition of supplemental application for devices because it did not include a PMA for a new use for a device on the market under section 510(k) of the act (21 U.S.C. 360(k)).

Because there are no supplemental applications for 510(k) devices, FDA could have interpreted the statute to exclude all 510(k) devices from the scope of the rule. FDA drew a distinction between those that require a new 510(k) and those that require a PMA because the agency determined that this was similar to the distinction between a supplemental NDA and an NDA (i.e., a supplemental NDA and a 510(k) are filed on products about which the agency has some accumulated knowledge and experience such that it is not required to start its review from scratch; an NDA and a PMA are filed for products about which the agency has no such accumulated knowledge or experience upon which to base a decision).

FDA disagrees with the comment that an original PMA submission should be included in the definition of ''supplemental application'' for a device that entered the marketplace through the 510(k) process. The 510(k) process and the PMA process are designed to provide different ways to market regulated products, are supported by a different extent and kind of data, and are predicated on different concepts of how to assure consumer protection.

A product entering the market via the 510(k) process does so because the agency agrees with the sponsor that the new device is substantially equivalent to a device commercially distributed before May 28, 1976, or to a newer predicate device for the same intended use. For a 510(k) product, the consumer protection objective of the act is met in part by the accumulated experience with the predicate devices and the review and establishment of the device category in the appropriate class and a modicum of device specific information. Information on manufacturing and premarket assurance of conformance to good manufacturing practices (GMP's) are not addressed. The agency does not, in the case of a 510(k), make an individual product determination of safety or effectiveness.

The act requires a PMA for a device for which there is a new intended use with no predicate, or which raises new issues of safety and effectiveness. Evidence required under a PMA is substantial and the sponsor must show, through the use of well-controlled clinical trials or, at the discretion of the agency, other valid scientific evidence, that there is a reasonable assurance the product is safe and effective for its intended use. As part of its review of a PMA, FDA reviews and audits clinical trial information and the GMP's employed by the manufacturer.

Allowing an original PMA submission to be regarded in this context as a supplement for a device already marketed under a 510(k) would undermine the statutory and regulatory requirements established to ensure the safety and effectiveness of products subject to PMA's. It would be analogous to applying the dissemination provision to new devices that were never legally marketed. For a PMA product, a new intended use supplement is intended to provide the agency with additional data supporting a new use for an approved device. It relies, in large part, on information previously reviewed regarding product materials, biocompatibility, design, performance, and basic safety data. For a 510(k) product, a PMA would not be providing additional information; it would be providing all of the information.

To illustrate, a product not currently marketed, but that was marketed as a general use tool without any known labeling or identified product specific intended use in the 1960's preamendment period may be re-introduced through a 510(k) for that same (implied) intended general tool use (e.g., it ablates or thermally destroys tissue). The product will be regarded as an unclassified preamendment product. If a manufacturer wished to market it for a specific intended purpose where that new purpose creates a new use with attendant questions of safety and effectiveness of the new use, it must do so through a PMA. In a recent instance, a company sought to market its unclassified preamendment product, an interuterine probe for a cryosurgery machine (using freezing to thermally destroy tissue), for ablation of the uterine endometrium with ultrasound control of the location and extent of tissue being frozen to control excessive menstrual bleeding. By moving to a tissue and anatomic specific intended use and indication, as well as by incorporation of a new (external) control procedure, the manufacturer has created a new intended use. The product's underlying safety and manufacture have never been evaluated. Even the presumption that ultrasound

measurement of the extent of tissue being frozen accurately predicts the extent of tissue necrosis and allows proper positioning of the probe remains unevaluated. Nevertheless, the comments would argue that this product could be the subject of an article or text disseminated under section 401 of FDAMA.

In passing section 401 of FDAMA, Congress intended to provide health care practitioners important scientific information about unapproved uses of approved products. The risks to the public of disseminating information in a case such as that described previously are closer to the risks from instances where there has never been an approved product than those for a new use of a previously approved product. FDA believes that these risks are far greater than those authorized by section 401 of FDAMA.

2. Subpart B—Information To Be Disseminated

a. Information that may be disseminated (§ 99.101). Proposed § 99.101 discussed the types of information concerning the safety, effectiveness, or benefit of a new use that a manufacturer may disseminate. For example, the proposal required (among other things) that the written information to be disseminated concern a drug or device that has been approved, licensed, or cleared for marketing by FDA and be in the form of an unabridged reprint or copy of a peer-reviewed scientific or medical journal article or an unabridged reference publication that pertains to a clinical investigation involving the drug or device and that is considered scientifically sound by experts who are qualified to evaluate the product's safety or effectiveness. Proposed § 99.101 also described criteria for determining whether the information to be disseminated is false or misleading, whether a clinical investigation is ''scientifically sound,'' and whether a reprint or copy of an article or reference publication is ''unabridged.''

20. One comment urged FDA to include a 60-day window in advance of a drug's Prescription Drug User Fee Act date during which time a manufacturer could submit proposed material for review. In other words, the comment urged FDA to accept dissemination materials for review before a drug has been approved.

FDA declines to adopt this approach. The statute does not direct FDA to accept submissions on products that have not yet been approved or cleared. If FDA accepts submissions on products that have not yet been approved or cleared, it may be wasting resources reviewing submissions on products that never get approved or cleared.

21. One comment urged FDA to make clear that this part does not permit the verbal dissemination of unapproved use information. Another comment suggested that companies that disseminate information on a new use should be permitted to discuss the clinical investigation that is the subject of the disseminated materials with the recipient.

FDA agrees with the first comment that neither this part nor section 401 of FDAMA, would permit the verbal dissemination of information about unapproved uses. Section 551(a) of the act and § 99.101 refer clearly and specifically to ''written'' information. Therefore, a manufacturer (or its representatives or agents) is not permitted to discuss with a recipient the clinical investigation that is the subject of the written materials disseminated under this part.

22. Several comments asked whether Internet or electronic dissemination would be permitted under this part.

Although, as set forth previously, FDA agrees that the provision was not meant to cover verbal dissemination, it could cover electronic dissemination. However, a manufacturer seeking to disseminate information electronically would have to ensure that all of the requirements under this part could be met for electronic dissemination. For example, the manufacturer would have to ensure that the recipients of the information are appropriately limited and that all of the required information and disclosures can be attached in accordance with this part. FDA may, in the future, issue guidance on this subject.

23. One comment noted the importance of requiring manufacturers to disseminate unabridged journal articles so that information from a clinical study is not pulled out of context or released without all relevant data.

FDA agrees with this comment. Both the statute and the regulation require that a journal article or reference publication disseminated under this part be unabridged.

24. Several comments objected to the requirement that a reprint or copy of an article be published prior to submission for FDA for review. These comments argued that manufacturers should be allowed to send FDA final manuscripts. Another comment opposed allowing submissions to include manuscripts or preprints of articles that have been accepted for publication. This comment stated that it could take months for these manuscripts to be published and that they might be submitted before the peer-review process is complete.

FDA understands manufacturers' desire to disseminate new use information as quickly as possible. However, section 552 of the act (21 U.S.C. 360aaa-1) requires that the peer-reviewed journal articles disseminated under this part be published. If FDA were to accept manuscripts before publication, it could not be sure that what gets published, and then disseminated, is exactly what it was given to review. The agency might not even be sure that the peer-review process has been completed. FDA does not have the resources to verify this information or to conduct duplicative reviews. Therefore, FDA is not revising the rule to permit submission of unpublished manuscripts.

25. Several comments took issue with the statement in the proposal that information can be false or misleading if it includes only favorable publications. These comments argued that dissemination should not be prohibited if the only information that has been published is favorable and the research is scientifically rigorous. These comments noted that FDA should make clear that a single favorable publication can be disseminated if it is objective, balanced, and discusses appropriate safety information. One comment noted that a more appropriate manner in which to state the issue would be to cite the exclusion of an unfavorable publication as the example.

FDA agrees that new use information is not necessarily without balance or misleading just because there is no unfavorable information disseminated with it and FDA did not intend to suggest the contrary. FDA agrees that it would be inappropriate to find a favorable article misleading just because it is disseminated without an unfavorable publication when no unfavorable publication exists. What FDA will be looking for is whether the manufacturer has failed to include unfavorable information that exists and that is necessary to provide balance. FDA has revised the rule to clarify this point.

26. One comment said that proposed § 99.101(a)(4) was unclear on what ''other information concerning risks and adverse effects that are or may be associated with the new use'' a company would have to include to ensure that the disseminated information is not false or misleading.

The other information refers to the additional information that FDA can require under § 99.103(a)(4). FDA has revised the rule to clarify this point.

27. Proposed § 99.101(a)(5) required that the disseminated information not be derived from clinical research conducted by another manufacturer unless the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination.

One comment noted that the rule should clarify that contracts or agreements between sponsors may specify how the data are to be used by the sponsoring companies. In other words, cosponsoring companies should be responsible for maintaining their own agreements without FDA input. Several other comments opined that once a peer-reviewed article is published, it is in the public domain and a sponsor should be able to pursue use of the data published by the original sponsor (i.e., without first obtaining permission) as long as proper credit is given. One comment asked FDA to clarify the rule to show that research conducted by an independent academic or similar organization can be disseminated if the information meets the standards for dissemination and is legally available for such use.

Section 551(b)(3) of the act prohibits the dissemination of information derived from research conducted by another manufacturer without that other manufacturer's permission. The fact that an article has been published does not eliminate the need to get permission from the researching company. If it did, this requirement in the statute would be meaningless because all information disseminated under this part must be published. Therefore, FDA declines to revise the rule to permit the dissemination of all published articles reporting on research conducted by another manufacturer without that manufacturer's permission. However, FDA agrees that cosponsoring companies can make agreements without FDA's input and that research conducted by independent parties does not, by the terms of the statute, require that party's permission.

28. One comment noted that reference publications will include many unapproved use discussions that reflect research conducted by other manufacturers and that proposed § 99.101(a)(5) would appear to make the disseminating company get permission from every one of those manufacturers.

As set forth in the proposal, FDA expects that manufacturers that disseminate reference publications under this part will flag the section of the text that describes the clinical investigation of a specific unapproved use (otherwise, they would have to commit to study all of the unapproved uses discussed in the reference publication). Therefore, FDA would expect that a manufacturer would be required only to seek the permission of another manufacturer if that other manufacturer conducted the study for that specific discussion of an unapproved use.

29. Proposed § 99.101(b)(1) provided that the determination of whether a clinical investigation is considered to be ''scientifically sound'' will rest on whether the design, conduct, data, and analysis of the investigation described or discussed in a reprint or copy of an article or in a reference publication reasonably support the conclusions reached by the authors. It further provided that a clinical investigation described or discussed in an article or reference publication must include a description of the study design and conduct, data presentation and analysis, summary of results, and conclusions pertaining to the new use. The proposal also stated that a clinical investigation presented in a format that does not represent a reasonably comprehensive presentation of the study design, conduct, data, analyses, and conclusions (e.g., letters to the editor, review abstracts, abstracts of a publication) would not qualify for dissemination under this provision.

The preamble to the proposal provided that in order to provide a basis for determining whether the conclusions are reasonably supported and the findings represent evidence of safety and effectiveness of the new use, the article or reference publication should provide, where applicable, evidence that the investigation: (1) Was prospectively planned; (2) enrolled an appropriately defined and diagnosed patient population for the specific clinical condition of interest; (3) accounted for all patients enrolled, including all patients who discontinued therapy prematurely; (4) utilized clinically meaningful endpoints or utilized surrogate endpoints that are reasonably likely to predict safety and effectiveness; (5) used a well described treatment regimen with a clear description of dose, schedule, duration, and route of administration; (6) used an appropriate control group or made reference to an appropriate historical control; (7) collected and reported adequate information on adverse experiences, and the need for dose reductions and treatment interruptions due to toxicity; and (8) was analyzed in a scientifically appropriate manner. (See 63 FR 31143 at 31146 and 31147.)

Some comments supported FDA's interpretation and applauded the agency's efforts to ensure that journal articles and reference publications are scientifically sound. These comments noted that FDA's interpretation reflected what is required by most peer-reviewed journals.

In contrast, a number of comments objected to FDA's approach. Some of these comments objected to FDA making any determination that an article or reference publication is scientifically sound. They stated that it was not Congress' intent to have FDA ''do its own peer review.'' Others criticized the criteria set forth in the proposed codified language and/or the eight criteria in the preamble to the proposal. They argued that FDA would be requiring more detail than is ever found in articles or reference publications and/or that FDA's standard is akin to that for a supplemental application. One comment said that FDA should require only enough detail to determine if the article or publication is scientifically sound. One comment urged FDA to adopt a broader definition of scientifically sound by removing the specific requirements, i.e., prospectively planned, and recognizing the value of scientifically sound studies as long as any limitations (e.g., epidemiological data) are fully disclosed. One comment said that FDA should require the journal article to include the ''typical level of detail'' and, if it does not, then the company should be able to attach it to the article. Several comments opposed the specific exclusion of abstracts. Finally, a number of comments specifically criticized the requirement that the clinical investigation be prospectively planned.

FDA has a role to play with respect to whether an article or reference publication is scientifically sound. The statute includes a requirement that the disseminated article or reference publication pertain to a clinical investigation that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved. FDA believes that this provision indicates that Congress meant for FDA to look at whether experts would find that the article or publication is about an investigation that experts would consider to be scientifically sound. However, FDA also believes that its role in determining whether an article or publication is scientifically sound is limited. This approach is consistent with the proposed rule and FDA fully expected that most journal articles about a clinical investigation from reputable peer-reviewed journals would meet the definition of scientifically sound set

forth in its proposal. Nevertheless, to ensure that the provision will be implemented consistent with congressional intent, FDA is revising § 99.101(b)(1) to provide that FDA will find that all journal articles and reference publications (as those terms are defined in § 99.3) are scientifically sound except: (1) Letters to the editor; (2) abstracts of a publication; (3) those regarding Phase 1 trials in healthy people; (4) flagged reference publications that contain little or no substantive discussion of the relevant clinical investigation; and (5) those regarding observations in four or fewer people that do not reflect any systematic attempt to collect data, unless the manufacturer demonstrates to FDA that such reports could help guide a physician in his/her medical practice.

Section 552(a)(2) of the act prohibits the dissemination of information that is false or misleading. That provision prohibits the dissemination of journal articles and reference publications that contain conclusions that are not supported by the study results. FDA has revised § 99.101(a)(4) accordingly.

30. One comment asked what FDA would do if an article discussed multiple unapproved uses, but the manufacturer wanted to focus on just one unapproved use.

FDA expects that there may be articles that discuss multiple unapproved uses and that such articles may be disseminated only if the requirements are met for each of those uses. There also may be instances when an article discusses multiple unapproved use(s), but there is one (or more) predominant unapproved use(s) discussed in the article. Under certain circumstances, it may make sense for the manufacturer to have to meet the requirements set forth in this part only for the predominant use(s). However, FDA will have to make this determination on a case-by-case basis.

31. One comment argued that dissemination of reference publications is not consistent with the purpose of section 401 of FDAMA because, by their very nature, reference publications are considerably out of date at the time of their publication. The comment further opined that because the authors do not report the methods used to assess the current scientific literature, reference publications should be considered the authors' opinion and thus, not scientifically sound.

FDA agrees that many reference publications may not be up to date. However, Congress did include reference publications within the scope of section 401 of FDAMA. There is no basis to presume that all reference publications are not scientifically sound.

32. Several comments opposed the requirement that disseminated information in the form of a reference publication ''pertain to a clinical investigation regarding the drug or device.'' Instead, they argued, the reference publication should ''include information about'' such a study. Some comments interpreted this to mean that the study should meet all of the criteria to establish scientific soundness, but the information about such a study should not be required. One comment said that the language means that the information needs to be based on a scientifically sound clinical investigation, it need not be about or describe such clinical investigation.

Both the act and this part provide that reference publications must ''include information about a clinical investigation.'' However, this does not mean that the information about that clinical investigation should be any less complete than the information included in a journal article. It means only that the text may have a lot of additional information that is not about the clinical investigation. The idea behind the dissemination provision is that physicians and other recipients be in a position to make treatment decisions based on published reports of clinical trials. If the information that is disseminated gives them little or no information about the actual trial, then it would be difficult to argue that they have a reasonable basis upon which to make such treatment decisions.

33. A number of comments argued that the proposal has written reference publications out of the statute by requiring the same level of detail as would appear in journal articles. One comment said that FDA should accept the dissemination of peer-reviewed reference publications. Some comments argued that the proposal would make text book dissemination more difficult than it was prior to passage of FDAMA and that FDA should adopt a final rule that is consistent with its existing reference text guidance or it should leave that guidance in place. One comment argued that the statute makes it clear that FDA must allow the dissemination of reference publications that meet the requirements of the statute and that the agency's decision to issue a guidance document on this issue is not an option.

As set forth previously, FDA does not believe that Congress meant that reference publications disseminated under this part could have less detail about clinical investigations than journal articles. In addition, reference publications are not subject to classic peer-review. Therefore, FDA rejects the comment that FDA accept all peer-reviewed reference publications. As discussed in the preamble to the proposal, however, FDA recognizes that it will be difficult for many reference publications to meet the statutory criteria. Moreover, as set forth in many of the comments, the new statutory scheme in most respects makes it more difficult to disseminate reference publications than was possible before FDAMA. Thus, FDA plans to permit companies to distribute unabridged reference publications (as defined in the statute and § 99.3(i)) without meeting all of the requirements set forth in this part if the company does not focus on or point to a specific unapproved use in the publication and it includes a disclaimer that the publication includes information about unapproved uses. (Cf. Guidance for Industry Funded Dissemination of Reference Texts (61 FR 52900, October 8, 1996). The agency was enjoined from applying this guidance document in *WLF* v. *Friedman*. FDA sought clarification on the scope of the order in that case through a motion to amend the judgment.) FDA plans to issue guidance on this issue at some time in the future following clarification by the court. Of course, manufacturers that want to focus or point to a specific unapproved use will have the option of doing so by meeting the requirements set forth in this part.

34. One comment argued that Congress intended for manufacturers to be able to disseminate reference publication chapters.

Section 552(a)(1) of the act clearly requires that the reference publication be unabridged. A chapter from a textbook does not meet this requirement.

35. Proposed § 99.101(b)(2) provided that journal articles and reference publications disseminated under part 99 cannot be disseminated with any information that is promotional in nature. One comment strongly agreed with the concept of prohibiting promotional material to be distributed with scientific information on a new use. One comment opposed the concept, stating that there is no policy or legal rationale for prohibiting companies from distributing information on approved uses with these reprints. A number of comments requested clarification of this statement. These comments were concerned that it could preclude a sponsor from delivering a promotional piece on a labeled use during the same office visit or detail. These comments suggested that FDA

clarify that so long as the promotional material concerns an approved use and is kept physically distinct from the unapproved use information, FDA would not consider the two to be distributed together.

FDA did not intend to prohibit a sponsor from delivering promotional pieces on an approved or cleared use during an office visit or detail in which it has delivered information on an unapproved use. Any unapproved use information, however, must be kept physically distinct from the promotional materials, and the sponsor may not verbally promote the unapproved use or include materials about the unapproved use, beyond those permitted or required under this part.

b. Mandatory statements and information (§ 99.103). Proposed § 99.103 described the information that must accompany the journal article or reference publication. For example, it required a prominently displayed statement disclosing (among other things) that the information being disseminated is about a use that has not been approved or cleared by FDA and is being disseminated under section 551 *et seq.* of the act and, if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the dissemination. It also required the official labeling and a bibliography of other articles to accompany the disseminated information. In addition, the proposal described what is meant by a ''prominently displayed'' statement by setting forth criteria that are consistent with the agency's regulations on prescription drug advertising (§ 202.1(e)(7)(viii)) and labeling (21 CFR 201.10(g)(2)). Proposed § 99.103 required the statement that the use has not been approved and the additional information required by FDA to be attached to the front of the disseminated materials and that all other mandatory information be attached to the disseminated information.

36. Although some comments supported FDA's position on mandatory statements, there were others that thought the proposal was unduly restrictive. For example, although some comments supported the requirement for a uniform statement disclosing that the new use has not been approved by FDA, there were a number of comments that thought manufacturers should be allowed to use alternative language to convey this message. One comment specifically objected to the phrase ''and is being disseminated under section 551 of the Federal Food, Drug, and Cosmetic Act.'' This comment said that the phrase was unnecessary and could be confusing.

FDA continues to believe that it is important to have a uniform disclosure stating that the new use has not been approved by FDA. Different statements can be confusing and recipients of the information may believe that they have different meanings. FDA agrees, however, that the phrase: ''and is being disseminated under section 551 *et seq.* of the Federal Food, Drug, and Cosmetic Act'' is unnecessary and has therefore dropped it from the final rule.

37. One comment stated that clarification is needed regarding articles that discuss more than one use because, as written, § 99.103(a)(1)(i) uses singular and plural forms in a way that is confusing.

FDA agrees that clarification was needed and has revised the final rule accordingly.

38. Proposed § 99.103(a)(1)(iii) required a statement disclosing any authors who have a significant financial interest in the manufacturer. One comment noted that, although the disclosure is appropriate, the final rule should make clear that such disclosure be in line with the level required by the rule on financial disclosure and should apply only to the financial interests at the time the study was conducted and not the author's current interest.

In the preamble to the proposed rule, FDA stated that an author would have a significant financial interest in a manufacturer when there is a relationship that may give rise to actual or perceived conflicts of interest and that when there is a question as to whether a relationship is significant, it should be disclosed (see 63 FR 31143 at 31147). Manufacturers may consult the final rule on financial disclosure by clinical investigators (codified at 21 CFR part 54) to learn the types of financial interests of greatest concern to the agency. However, because the purposes and terminology of this final rule and the final rule on financial disclosure by clinical investigators are different, manufacturers should consult the provisions of this final rule for the requirements that apply to disclosures regarding authors. FDA agrees that the financial disclosure should not necessarily apply to the author's current financial interest. FDA believes, however, that it should apply to the author's financial interests during the time the study was conducted up through 1 year after the time the journal article or reference publication was written and published. FDA has revised the final rule to reflect this time limitation. FDA's revision is consistent with part 54.

39. One comment urged FDA to require that the statement that there are products or treatments that have been approved or cleared for the use that is the subject of the dissemination list the names of other drugs that have been approved by FDA. Another comment asked whether such statement should address adjuvant or supporting therapies.

FDA's regulation tracks the statute, which does not require a manufacturer to identify the specific products that have been approved or cleared for the new use or the adjuvant or supporting therapy for the new use. (See section 551(b)(6)(A)(v) of the act.) Although FDA can see the benefit of having those specific product names listed, it would be difficult to develop a complete and accurate list. Moreover, the information could be misleading if the manufacturer merely provided a list of names. FDA also does not believe that the statement should address adjuvant or supporting therapies. The idea behind the disclosure is to let health care practitioners and other recipients know that approved/cleared alternatives exist. Therefore, FDA is retaining the requirement that the manufacturer only disclose that such approved/cleared products exist.

40. Proposed § 99.103(a)(2) provided that the manufacturer must attach the official labeling of the product to the unapproved use information. In the preamble to the proposed rule (63 FR 31143 at 31147), FDA noted that devices, unlike drugs, do not always include a package insert in the same form and manner as drugs. Therefore, the agency would expect device manufacturers to provide the same information that is generally found in package inserts, namely: (1) The name of the device, including its trade or proprietary name; (2) the manufacturer's name, address, and telephone number; (3) a statement of intended use, including a general description of the diseases or conditions that the device is intended to diagnose, treat, cure, or mitigate; (4) a description of the patient population for which the device is intended; (5) a description of indications that have been approved or cleared by FDA; (6) a description of any limitations or conditions that have been placed on the sale, distribution, or use of the device; and (7) all warnings, contraindications, side effects, and precautions associated with the use of the device.

One comment suggested that a device's official labeling be interpreted as: (1) The package insert for the device; (2) the accompanying documents that a manufacturer distributes with its legally

marketed device to comply with the requirements of 21 CFR 801 or 809.10 for in vitro diagnostic products; or (3) the new labeling vehicle created by a manufacturer that contains the listed items from the preamble.

FDA agrees that this interpretation of official labeling for devices is appropriate provided the third option is used only when the first two options are not available or not feasible and provided the third option includes only the information listed in the preamble (i.e., no promotional statements or representations are included).

41. Proposed § 99.103(a)(3) required the manufacturer to attach a bibliography of other articles (that concern reports of clinical investigations both supporting and not supporting the new use). One comment noted that a bibliography is not required every time—only when one is not present in the disseminated information. Another comment stated that the bibliography requirement is vague regarding what needs to be included and under what circumstances a bibliography included in the publication is sufficient.

FDA's proposal provided that the manufacturer need not include a separate bibliography if the disseminated information already includes a bibliography that meets the requirements set forth in § 99.103(a)(3). The bibliography requirement would be met by a list of all other published articles from scientific reference publications or scientific or medical journals that discuss clinical investigations and are specific to the new use discussed in the disseminated information. The bibliography must include articles about clinical investigations that both support and do not support the new use and it must identify which articles relate to the new use. A bibliography already included with the disseminated information would meet this requirement only if it includes all other such published articles. The manufacturer would still have to include its search strategy to show that it took reasonable steps to ensure that the bibliography includes all relevant published articles as described in § 99.103(a)(3).

42. Proposed § 99.103(a)(4) required a manufacturer to include any additional information required by FDA, including objective and scientifically sound information pertaining to the safety or effectiveness of the new use that FDA determines is necessary to provide objectivity and balance, including information that the manufacturer has submitted to FDA or, where appropriate, a summary of such information, and any other information that can be made publicly available; and an objective statement prepared by FDA, based on data or other scientifically sound information, bearing on the safety or effectiveness of the new use of the product.

Several comments noted that this provision should specify that FDA must provide the manufacturer notice and an opportunity to meet before requiring such information.

FDA agrees that a manufacturer must be provided notice and an opportunity to meet before being required to include this additional information. Redesignated § 99.301(a)(2) provides this opportunity and FDA has revised the final rule at § 99.103(a)(4) to include a reference to § 99.301(a)(2).

43. Several comments opposed the requirement that the statement that the use has not been approved and the additional information required by FDA be attached to the front of the disseminated materials and that all other mandatory information be attached to the disseminated information. One comment suggested that the FDA-required information be attached to the back, and that FDA permit the use of a sticker on the front of the disseminated material stating that the FDA-required information is attached to the back.

FDA believes that it is important to permanently affix the statement indicating that the disseminated information is about an unapproved use to the front of the materials. The recipients of such materials should know, in advance, that they are reading information about an unapproved use. However, FDA agrees that it could be appropriate to attach the additional information required by FDA to the back of the materials, provided there is a sticker or notation on the front referring the recipient to that information. The agency has amended § 99.103(a)(4) accordingly.

FDA also believes it is important to attach the remaining information to the disseminated materials. Congress included this mandatory information because it determined that it was important for the recipient to receive it. If such information is not attached, it can easily be separated from the disseminated material and never seen by the recipient. This is the information that helps to ensure that the disseminated materials are objective, balanced, and not misleading.

44. Although some comments stated that the criteria in proposed § 99.103(c) for determining whether the mandatory information is prominently displayed are appropriate, others opposed the factors that FDA will consider in determining whether the mandatory information is prominently displayed. The latter comments argued that manufacturers should retain some flexibility and discretion in this area.

FDA's approach is flexible. Section 99.103(c) sets forth the factors that FDA will consider and provides that the required statements shall be outlined, boxed, highlighted, *or otherwise graphically designed and presented in a matter that achieves emphasis or notice and is distinct from the other information being disseminated* (emphasis added). Such an approach is not as proscriptive as the comments imply. FDA has retained this approach in the final rule.

45. One comment suggested that FDA permit manufacturers to post information, such as balancing articles required by FDA, on the Internet so long as the Internet address is prominently displayed on the information that was disseminated. The comment said that this would reduce paperwork burdens and provide a continuous source of current information.

FDA does not think that it would be appropriate for manufacturers to use the Internet to balance a published reprint disseminated in hard copy format or to provide recipients of unapproved use information with only part of the information required by the statute and regulations. The idea behind the provision was that physicians would receive, at one time, a balanced package. Such balance would not be achieved if a manufacturer could hand a physician an article and then advise the physician that he/she has to take steps on his/her own to retrieve the balancing information.

46. Several comments urged FDA to require manufacturers to provide patient labeling for drugs that are the subject of the disseminated information. The comments noted that such labeling should identify the drug by name, notify consumers that the drug has been promoted for an unapproved use, and indicate FDA-approved uses for the drug. They further argued that the patient labeling must include information about the potential risks of the drug and meet the quality and content standards of FDA's 1995 proposed Medication Guide rule. This comment said that FDA-approved patient labeling must be in commercial distribution at the level of the pharmacy before dissemination under this part can begin. One comment stated that the labeling should state that these products are not tested in certain populations and should say ''use at your own risk.''

FDA recognizes the importance of providing consumers access to information about the products they use. Since 1968, FDA has occasionally required and often encouraged manufacturers to produce patient labeling for certain prescription drugs. However, the comments' request for additional patient labeling on drugs that are the subject of information disseminated under part 99 is outside the scope of section 401 of FDAMA.

47. Several comments argued that the lack of availability of pediatric studies on a particular use should be clearly and prominently stated in the information being disseminated to health professionals. These comments also urged FDA to require an additional statement for drugs that have not undergone pediatric testing: ''Safety and effectiveness in pediatric populations have not been established for this product for the use that has been approved by FDA or for the use suggested by this information.''

The suggestion that for drugs and devices that have not undergone pediatric testing, the disseminated information should include a statement to that effect is beyond the scope of this rule. However, for unapproved pediatric uses that are the subject of the information being disseminated, there will be a statement that the use has not been approved or cleared by FDA.

c. Recipients of information (§ 99.105). Proposed § 99.105 identified who may receive information disseminated under this part. Specifically, a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency could receive information disseminated under part 99.

48. Several comments urged FDA to add pharmacists to the list of recipients of information under this part.

As previously discussed, section 401 of FDAMA specifically lists who can receive the unapproved use information under this provision. To the extent that pharmacists are included in the definitions of ''health care practitioner,'' ''pharmacy benefit manager,'' ''health insurance issuer,'' or ''group health plan'' (see § 99.3), they will be included as recipients of this information.

3. Subpart C—Manufacturer's Submissions, Requests, and Applications

a. Manufacturer's submission to the agency (§ 99.201). Proposed § 99.201 described the contents of a manufacturer's submission to FDA. This submission would be made 60 days before disseminating information on an unapproved or new use and would include items such as a copy of all of the information to be disseminated, all other clinical trial information that the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and, if a supplement for the new use has not been submitted, a certification that the manufacturer will submit a supplement or an application for an exemption from the requirement to submit a supplement. The proposal also discussed what types of information must be submitted when the certification provides that the studies have been completed or that studies will be conducted as well as the contents of the certification. Proposed § 99.201 also provided that the 60-day period begins to run when FDA receives a complete submission.

49. One comment agreed that manufacturers should have to submit any clinical trial information that they have relating to the safety and effectiveness of the new use. However, another comment argued that the requirement for any clinical trial information is far more exhaustive than that required by the statute.

Section 551(b)(4)(B) of the act requires manufacturers to submit ''any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information.'' Proposed § 99.201(a)(2) tracked this requirement and described what it included. In the final rule, FDA is making clear that, for effectiveness information, the requirements are limited to information on clinical investigations of the new use; safety information is broader and must include all relevant new data from human experience.

50. One comment urged FDA to require manufacturers to report only those adverse experiences that they have received directly because companies do not have access to the details of cases submitted to other manufacturers and thus, are unable to evaluate the reports. That same comment stated that FDA should permit adverse experience reports to be submitted in summary or tabular form rather than as individual case reports. Several other comments requested the ability to reference files that FDA already has about adverse experiences. Finally, one comment noted that the search requirements for adverse reports should be more clearly delineated.

Under the statute and these regulations, manufacturers would have to submit only those adverse experience reports that they have. This would include reports originally made to other manufacturers. If the reports were originally submitted to other manufacturers and the disseminating manufacturer does not know whether to attribute the adverse experience to the new use, it should submit the information to FDA. Manufacturers can submit adverse experience reports in summary or tabular form if FDA already has the individual case reports. With respect to search requirements for postmarket adverse event reports, FDA does not think that it is necessary to be any more specific. Manufacturers gather this information on a regular basis.

51. One comment said that the literature search requirements in § 99.201(a)(3) should be more clearly delineated. Several comments stated that the requirement for the submission of a search strategy is not required by statute and should be eliminated because it is unnecessary and burdensome and could delay the process.

FDA believes that it is necessary to include the search strategy. This is how FDA will be able to determine whether the bibliography meets the statutory criteria. FDA has revised § 99.201(a)(3), however, to clarify the bibliography search strategy requirements.

52. FDA, on its own initiative, revised § 99.201(a)(4)(i)(B) and (a)(4)(ii)(B) to clarify that, for purposes of computing time periods that begin on the date of initial dissemination, FDA will look to the date on which dissemination can begin. This clarification was necessary because FDA will not know when a manufacturer actually begins to disseminate materials. The same revision was made to §§ 99.203(b) and 99.401(b).

53. Proposed § 99.201(a)(4)(ii) required a manufacturer that has planned studies that will be needed for a supplement to submit the proposed protocols and schedule for conducting such studies. The protocols must comply with FDA's IND or investigational device exemption (IDE) regulations. One comment asked FDA to clarify whether a manufacturer who has planned studies and wishes to disseminate information must submit a complete IND or IDE in addition to the information required in a submission under this rule. One comment stated that if the protocols are to be treated as IND's, IDE's, or amendments thereto, the manufacturer should be able to commence the studies within 30 days unless the agency places the study on clinical hold. The same comment said that if the agency does not place a

clinical hold on the protocol within 30 days, the agency should not be able to determine that the protocols are inadequate on day 60 and if the protocol is put on clinical hold within 30 days, it should not be dispositive of the decision. The comment further stated that if the agency decides that the protocols are adequate, it should be bound by this decision and the final rule should reflect this. Finally, several comments urged FDA to permit manufacturers to cross reference IND's and IDE's rather than resubmitting such information.

FDA intends that the protocols for planned studies under this provision be submitted in compliance with the IND or IDE regulations. However, a manufacturer will not be required to submit these materials twice. If a protocol has already been submitted to an IND or IDE, the IND or IDE can be cross referenced in the dissemination submission.

Moreover, FDA does not intend to change, in any way, the IND or IDE regulations, including the timeframes. If an IND or IDE is submitted and a clinical hold is not issued within 30 days, the manufacturer can commence the study or studies. However, the fact that FDA does not issue a clinical hold within 30 days, does not prevent FDA from determining, within 60 days, that a protocol is inadequate. FDA can issue a clinical hold at any time after the 30-day period if the requirements for issuing a clinical hold are met. If the protocol is put on clinical hold within 30 days, it may not be dispositive of the issue because the sponsor may remedy the reason for the clinical hold within the 60-day period. However, if the reason for issuing the clinical hold is not resolved, it will be dispositive of the issue. Finally, FDA is declining to revise the rule to provide that if the agency finds that the protocols are adequate, it will be bound by this decision. FDAMA addressed the issue of agreements regarding the parameters of the design and size of clinical trials. (See, e.g., section 505(b)(4)(C) or section 520(g)(7)(A) through (g)(7)(C) of the act (21 U.S.C. 360j(g)(7)(A) through (g)(7)(C)).) FDA will abide by these statutory directives.

54. Proposed § 99.201(a)(4)(ii) required a manufacturer that has planned studies that will be needed for the submission of a supplemental application for the new use to certify that it will exercise due diligence to complete such studies and submit a supplement within 36 months of dissemination. FDA has revised this section to reflect the possibility that FDA may determine, before the certification is submitted, that the studies needed to submit a supplemental application cannot be completed and submitted within 36 months. This change is further reflected in § 99.203.

55. One comment requested that the 36-month timeframe for submitting a supplement not override the time limits created under separate regulatory or statutory authority. This comment was concerned that if FDA finalizes its proposed 1997 regulation on pediatric research and it includes compliance dates for completing the pediatric studies that are less than 36 months, the 36-month period in this part not override that shorter timeframe.

As FDA has stated elsewhere in this document, nothing in this regulation is meant to change or supersede other regulatory requirements.

56. One comment asked FDA to clarify the submission requirements and FDA action requirements with respect to nonsignificant risk devices.

Protocols submitted for studies for devices considered to be nonsignificant will be reviewed by FDA only to ensure that the protocol for the study is consistent with the new use information to be disseminated. Manufacturers must present the protocol for the nonsignificant risk device study to an institutional review board (IRB) for approval before starting the study. (See 21 CFR 812.1(b)(1).) However, all reporting requirements under this part will apply to nonsignificant risk device studies.

57. One comment requested that the agency provide the sponsor an opportunity to meet with FDA promptly to review what changes can be made to the protocol to ensure that it meets requisite standards.

Sections 505(b)(4)(B) and 520(g)(7)(A) and (g)(7)(C) of the act provide sponsors with an opportunity to meet regarding their proposed protocols. Therefore, no changes to this rule are necessary.

58. One comment recommended that all statements submitted under this part be certified by an officer from the manufacturer's executive committee. Another comment recommended that the language in the certification should include ''to the best of my knowledge'' to reduce the risk that a certifying official could be penalized for an inadvertent mistake not within his/her knowledge.

The final rule requires that the manufacturer's attorney, agent, or other authorized official sign the submission. Although an officer from the manufacturer's executive committee may be an authorized official, FDA does not think it is necessary for the submission to be signed by such an officer. FDA also does not agree that it would be appropriate to include the words ''to the best of my knowledge'' in the certification. The attorney, agent, or other authorized official who signs the submission and certification on behalf of the manufacturer, and ultimately the manufacturer itself, is responsible for what is submitted to the agency under this part.

59. Proposed § 99.201(c) described the component in each FDA center that will receive a submission under this part. Several comments noted that it would be appropriate for the review divisions in the centers to also receive copies of the information submitted under this part.

In the final rule, FDA is retaining the requirement that the submissions go to a single office within each center. Those offices will forward the information to the appropriate review divisions within the agency. The regulation need not spell out all of FDA's internal procedures for processing these submissions.

60. One comment stated that FDA needs to clarify the required physical organization of the documents submitted under this part.

FDA does not think it is appropriate to include that kind of detail in this regulation. Nevertheless, FDA expects that materials in a submission will be organized and labeled in accordance with the submission requirements described in this part. If FDA subsequently determines that manufacturers need more guidance in this area, it will issue a guidance document.

61. A number of comments objected to proposed § 99.201(d), which provided that the 60-day (post submission) period shall begin to run when FDA receives a complete submission and that a submission shall be considered complete if FDA determines that it is sufficiently complete to permit a substantive review. These comments argued that FDA would use this provision to extend the 60-day time period. The concern was that FDA would, on day 59, advise a manufacturer that their submission was not complete and therefore the 60-day time period had not begun. The comments said that Congress meant for FDA to give a final answer within the 60-day time period.

As further described below, FDA is committing to give manufacturers a final decision within 60 days. FDA has revised § 99.201(d) to provide that the 60-day period shall begin when FDA receives a manufacturer's submission, including, where applicable, a

certification statement or an application for an exemption.

62. A number of comments were made regarding the appropriateness of public disclosure of information submitted under this part. Some comments argued that both the fact of the submission and all information in the submission is confidential and should not be released. Other comments argued that all of the previous information should be public because the public, including the patient community, wants to be involved and has a right to know about a submission, the data in such submission, FDA action on the submission, what studies are being conducted, and the status of those studies. Several comments argued that upon receiving a submission, FDA should publish in the **Federal Register**, the citation for the article and the bibliography, and solicit additional published information that might be appropriate for dissemination. One comment argued that the public should have an opportunity to comment prior to FDA's granting approval for dissemination of information and that FDA should hold an advisory committee meeting and let the public participate in its decision on whether an exemption from the requirement to submit a supplement should be granted.

FDA declines to amend the rule to require a notice and comment process before permitting dissemination to proceed or before granting an exemption. However, the Freedom of Information Act (FOIA) and FDA's regulations will dictate what information submitted under this provision can be disclosed. Because the agency was required to issue this regulation within such a short period of time, it has been unable to fully examine all issues of disclosability. However, the agency will continue to examine these issues separately.

b. Request to extend the time for completing planned studies (§ 99.203).

Section 554(c)(3) of the act (21 U.S.C. 360aaa-3) describes two types of extensions of time regarding planned studies. Section 554(c)(3)(A) of the act provides that the 36 month period for completing planned studies and submitting a supplemental application may be extended by the Secretary of Health and Human Services (the Secretary) if the Secretary determines that the studies needed to submit such application cannot be completed and submitted within 36 months. This type of extension would be granted before such studies are begun. Section 554(c)(3)(B) of the act provides that the period for completing planned studies and submitting a supplemental application may be extended by the Secretary if the manufacturer submits a written request for the extension and the Secretary determines that the manufacturer has acted with due diligence to conduct the studies in a timely manner. The latter extension cannot exceed 24 months. Proposed § 99.203 set forth the procedures that a manufacturer must follow to request an extension of time for submitting a supplemental application and the content of a request for an extension. The provision covered only the extension in section 554(c)(3)(B) of the act.

63. The comments to this provision indicated that there was some confusion regarding the two different statutory procedures. Several comments asked FDA to more clearly set out the two procedures contemplated by the statute.

Although the statute specifically refers to a manufacturer request in connection only with the procedure described in section 554(c)(3)(B) of the act and FDA agrees that the agency can, under section 554(c)(3)(A), on its own initiative determine before the studies have begun that more than 36 months is needed, FDA believes that manufacturers will come to FDA and ask FDA to make a determination under section 554(c)(3)(A) of the act. Therefore, FDA has revised § 99.203 to establish procedures for the two different types of extensions. The first extension, set forth in § 99.203(a), relates to a request for an extension by the manufacturer at or before the time it submits its dissemination package to FDA because the 36-month period is not enough time to complete a study or studies of the new use and submit a supplemental application. Revised § 99.203(b) sets forth the procedures that a manufacturer must follow to request an extension of time for submitting a supplemental application after a study has begun and the content of a request for an extension.

c. Application for exemption from the requirement to file a supplemental application (§ 99.205). Proposed § 99.205 set forth what a manufacturer must submit when seeking an exemption from the requirement to file a supplemental application for a new use for purposes of disseminating information on that new use. It required the manufacturer to include an explanation as to why an exemption is sought and to include materials demonstrating that it would be economically prohibitive or unethical to conduct the studies needed to submit a supplemental application for the new use.

64. A number of comments supported the standards that FDA proposed to determine whether it would be economically prohibitive or unethical to conduct the studies needed to submit a supplemental application. Some noted that FDA's standards are consistent with congressional intent that exemptions be limited in scope and infrequent or rare. One comment argued that pediatric exemptions should be extremely rare. One comment stated that exemptions should never be granted.

FDA agrees that Congress intended that exemptions from the requirement to file a supplemental application for a new use be granted in limited circumstances (see H. Conf. Rept. No. 399, 105th Cong., 1st sess. at 100 (1997); 143 Congressional Record S9,837 (daily ed. Sept. 24, 1997) (Statement of the Managers)). There is nothing in the statute or legislative history that gives FDA authority to apply a different standard in the case of pediatric exemptions. Moreover, the act provides for exemptions, so FDA does not agree that such exemptions should never be granted. In light of the comments received to the standards set forth in its proposal (discussed in more detail below), FDA is adopting a different standard for the economically prohibitive exemption. Although, FDA is not changing the standard for the unethical exemption, it has, as discussed in the following paragraphs, clarified how it will apply that exemption.

Economically Prohibitive Exemption

Under proposed § 99.205(b)(1), a manufacturer seeking an exemption from the requirement to file a supplemental application on the basis that it would be economically prohibitive to conduct the needed studies would have to: (1) Explain why existing data, including data from the scientifically sound study described in the information to be disseminated, are not adequate to support approval of the new use; and (2) show, at a minimum, that the estimated cost of the necessary studies would exceed the estimated total revenue from the product minus the cost of goods sold and marketing and administrative expenses attributable to the product and that there are not less expensive ways to obtain the needed information.

Proposed § 99.205(b)(1) set forth the type of evidence that the manufacturer would have to include to meet the requirements for an economically prohibitive exemption. These included:

(1) A description of the current and projected U.S. patient population for the product and an estimate of the current and projected economic benefit to the

manufacturer from the use of the drug or device in this population. The estimate would assume that the total potential market for the drug or device is equal to the prevalence of all of the diseases or conditions that the drug or device will be used to treat and involve the following considerations: (a) The estimated market share for the drug or device during any exclusive market period, a summary of the exclusive market period for the product, and an explanation of the basis for the estimate; (b) a projection of and justification for the price at which the drug or device will be sold; and (c) comparisons with sales of similarly situated drugs or devices, where available.

(2) A description of the additional studies that the manufacturer believes are necessary to support the submission of a supplemental application for the new use and an estimate of the projected costs for such studies; and

(3) An attestation by a responsible individual of the manufacturer verifying that the estimates included with the submission are accurate and were prepared in accordance with generally accepted accounting procedures. The data underlying and supporting the estimates shall be made available to FDA upon request.

65. As set forth previously, some of the comments agreed with FDA's construction of ''economically prohibitive'' These comments argued that such exemptions should be granted rarely and that the criteria for such an exemption should be rigorous. One comment argued that the cost for the studies should substantially exceed revenues to qualify for the exemption. Several comments opposed such an equation.

FDA agrees that exemptions should be granted only in limited circumstances. As set forth below, however, FDA was convinced by the comments that the standard set forth in its proposal was inappropriate and has revised the standard.

66. A number of comments objected to how the agency proposed to determine what is economically prohibitive. First, they objected to the agency's use of the term ''rare'' in describing when such exemptions would be granted. One comment opined that Congress meant for the exemption to arise in a ''fair number of circumstances.'' Second, they objected to the absence of the criteria listed in the statute and report language from the standard set forth in the codified regulation. Third, they claimed that the proposed rule's standard for determining what is economically prohibitive is too high.

One comment argued that the exemption should be granted if it does not make economic sense to pursue a supplement. Others argued that it should be based on the revenue from the new use, not all uses of the product. Some argued that the standard should be whether the cost of the studies would exceed the revenues from the new use; others argued that it should be whether the cost of the studies exceeds the new use revenues that resulted from approval of the supplement (i.e., the increase in revenues from the new use that result from submission of the supplement). Several comments argued that FDA should automatically grant an exemption if the new use is for a rare disease or condition because for such use there is no reasonable expectation that the cost of developing and making available a drug for such disease will be recovered from sales in the United States of such drug. Several comments argued that the economically prohibitive exemption should automatically be granted if: (1) There is no market exclusivity for the product (from patent, orphan drug status, or Waxman-Hatch); or (2) the patient population likely to be served by the new indication will not exceed an established number (e.g., 1,000). One comment opined that interpreting ''prohibitive'' to mean anything other than the point at which an economically rational company will not pursue research ignores the needs of patients with rare disorders.

FDA agrees that Congress did not use the term ''rare'' in the legislative history. Nevertheless, Congress did state that exemptions to the requirement to submit a supplement would be appropriate only in ''limited circumstances,'' which in FDA's view implies fewer than in a ''fair number of circumstances.'' Moreover, Congress strongly emphasized the critical importance of getting information about new uses onto the label. Although FDA did not include the criteria listed in the statute and the legislative history in the standard for economically prohibitive, they were included as types of evidence that would be required to support the exemption.

FDA's proposed criterion did not focus solely on sales from the new use because the agency believed that there might be many circumstances where the cost of the study requirements would exceed the sales from just the new use. The agency explained that in some of these situations, even if it were not economically ''wise'' to conduct the studies, the cost would not rise to the level of being ''prohibitive.'' This view was judged consistent with the legislative history, which foresaw the granting of economic exemptions only in limited circumstances. The agency noted, however, that defining a practical ''economically prohibitive'' exemption was particularly troublesome, because it would be so difficult for the agency to assess cost and income projections. In view of these difficulties, FDA acknowledged that it was not certain that the proposed approach was optimal and sought comment on other possible ways to define economically prohibitive.

Unfortunately, the agency has received widely conflicting public comment on this issue and remains uncertain about the elements of a standard that would be most appropriate and effective in achieving the statutory goals. An approach that would grant automatic exemptions if: (1) The new use were for a rare disease or condition; (2) there was no market exclusivity for the product (from patent, orphan drug status, or Waxman-Hatch); or (3) the patient population likely to be served by the new indication would not exceed an established number (e.g., 1,000) would be inappropriate. Neither the statute nor the legislative history provide for automatic exemptions in these circumstances. Rather, they direct FDA to take both market exclusivity and population size into account. The legislative history made clear that the size of the patient population would not necessarily justify an exemption. In fact, the legislative history stated that an exemption based on the size of the patient population was intended to be the exception rather than the rule in cases of populations suffering from orphan or rare diseases or conditions. The legislative history made clear that FDA should consider the importance of getting products for these diseases or conditions approved. It noted that for many years, Congress has sought to encourage research into orphan diseases and support the approval of innovative drugs for their treatment. Congress, therefore, has directed FDA to recognize the vital importance of encouraging applications for new products intended to treat rare diseases and to examine very carefully whether an exemption from filing a supplemental application might hinder such research (see H. Conf. Rept. No. 399, 105th Cong., 1st sess. at 100 (1997); H. Rept. No. 310, 105th Cong. 1st. sess. at 62 (1997)).

Because the agency remains uncertain about the elements of a standard that would be most appropriate and effective, FDA plans to continue its search for a policy that would satisfy the congressional expectation of approving exemptions in only limited

circumstances, without foreclosing the dissemination of useful information by firms that could not otherwise conduct the needed studies. In the meantime, FDA will implement the statute by basing its evaluation of each exemption on a case-by-case determination of whether the cost of the study for the new use reasonably exceeds the total expected revenue from the new use minus the cost of goods sold and marketing and administrative expenses attributable to the new use of the product. This standard may not always meet a strict profitability criterion because it considers all new use revenues, rather than just the new use revenues that would result from approval of the supplement. Nevertheless, it is consistent with most of the comments submitted by the affected industry on this issue, it is consistent with the statutory directive, and it attempts to strike a fair balance between assuring the widest possible information dissemination while granting economic exemptions only in ''limited circumstances.''

The final rule sets forth the statutory standard and the information that FDA would need to make this case-by-case determination. This will include information about: (1) The cost of the study for the new use; (2) the expected patient population for the new use; (3) the expected total revenue for the new use minus the cost of goods sold and marketing and administrative expenses attributable to the new use of the product; (4) the amount of exclusivity for the drug or new use; and (5) other information that the manufacturer believes demonstrates that conducting the studies on the new use would be economically prohibitive.

As this revised criterion may significantly expand the number of exemption applications beyond that anticipated by the Congress, the agency is determined to review its experience with these requests as they are submitted and, if necessary, to contract with outside economic experts to help develop an approach that most appropriate and effective and workable for the agency.

67. A number of comments objected to the requirement to submit detailed financial data. These comments argued that manufacturers should be not required to submit highly sensitive and proprietary information. Others felt that FDA is not qualified to review and evaluate this data.

Congress directed FDA to grant an economic exemption only upon making a determination that conducting the studies and submitting a supplement would be economically prohibitive. FDA cannot make this determination without examining the relevant company data. Therefore, the final rule retains these requirements.

68. Several comments regarding FDA's approach to economic exemptions recommended that FDA require a manufacturer to submit a certified public accountant's (CPA's) opinion on the economic feasibility of filing a supplemental NDA. FDA could contest the claim by providing a CPA's statement to the contrary.

FDA declines to adopt this approach because it removes the agency from the statutorily-specified role of determining whether it would be economically prohibitive to conduct the studies.

69. One comment recommended that manufacturers be given the flexibility to present whatever information they determine is relevant to the ''economically prohibitive'' factor, that the manufacturer be able to use its own assumptions, and that each situation be evaluated on a case-by-case basis.

As set forth previously, FDA is adopting a case-by-case determination and has specified the information that is essential for this determination. Nevertheless, manufacturers are free to provide whatever additional information they think is relevant to the determination. This could include information that would explain why a study is so expensive to conduct. For example, one factor might be the difficulty of enrolling patients in a clinical investigation if the new use has become the standard of care.

70. Proposed § 99.205(b)(1)(ii)(A) stated that the estimated economic benefit for a drug or device shall assume that the total potential market is equal to the prevalence of the disease(s) or condition(s) that such product will be used to treat. Several comments argued that this assumption should be deleted because the potential market for the drug or device may be less than the prevalence of the disease in question if other therapies are likely to be used in some portion of the total patient population.

FDA agrees that this assumption should be deleted and has done so in the final rule.

71. One comment argued that the manufacturer should not be required to provide a ''justification'' of the price at which the drug will be sold. According to this manufacturer, only a projection is relevant.

FDA has to be able to determine whether the manufacturer's proposed price is reasonable. It may be that ''justification'' for the price is not appropriate. Therefore, in § 99.205(b)(ii)(C) of the final rule, FDA will seek an explanation of the price at which the drug or device will be sold.

72. One comment opined that permitting an exemption because of cost is an ethical decision because it is placing a monetary value on people's lives and safety.

FDA does not agree that an economically prohibitive exemption is placing a monetary value on people's lives and safety. The standard in FDA's regulation is intended to best effectuate the goals of the statute.

73. Proposed § 99.205(b)(1)(ii)(C) required a manufacturer to provide an attestation by a responsible individual of the manufacturer verifying that the estimates included with a submission are accurate and were prepared in accordance with generally accepted accounting procedures. In addition, the data underlying and supporting the estimates would have to be made available to FDA upon request. In the preamble to the proposed rule, FDA noted that it had considered requiring a report of an independent CPA with respect to the estimates and FDA solicited comment on whether such a report should be required in lieu of, or as an alternative to, the attestation that would be required by the proposal.

Some comments supported the submission of the CPA report discussed previously, others felt that such a report should not be required. Still other comments stated that the CPA report should be submitted in lieu of the underlying data or that the CPA should make the determination of economic feasibility instead of FDA.

As stated previously, FDA refuses to adopt a procedure by which it surrenders decision making to a CPA. However, FDA is not convinced that it is necessary to require a report of an independent CPA with respect to the estimates. Under § 99.205(b)(1)(iii), therefore, FDA will accept either an attestation by a responsible individual of the manufacturer or by a CPA verifying that the estimates included with a submission are accurate and were prepared in accordance with generally accepted accounting procedures.

Unethical Exemption

Proposed § 99.205(b)(2) required a manufacturer seeking an exemption on the basis that it would be unethical to conduct the studies needed to submit a supplement, to: (1) Explain why existing data, including data from the scientifically sound study described in the information to be disseminated, are not adequate to support approval of the new use; and (2) show that, notwithstanding the insufficiency of existing data to support the submission of a supplemental application for the

new use, the data are persuasive to the extent that withholding the drug or device in the course of conducting a controlled study would pose an unreasonable risk of harm to human subjects.

The proposed codified language provided that an unreasonable risk of harm would ordinarily arise only in situations in which the new use of the drug or device appears to affect mortality or irreversible morbidity. Evidence suggesting that the drug or device is the standard of care for the new use can add weight to an argument that conduct of a needed study or studies would be unethical.

To support its argument that the conduct of a needed study or studies would be unethical, the proposal provided that a manufacturer would need to address the possibility of conducting studies in different populations or of modified design (e.g., adding the new therapy to existing treatments or using an alternative dose if monotherapy studies could not be conducted).

The proposal further provided that in assessing the appropriateness of conducting studies to support the new use, the manufacturer may provide evidence that the new use represents standard medical treatment or therapy. Evidence that the new use represents standard medical therapy can be one element of an argument that studies cannot ethically be conducted, but the persuasiveness of available data is equally important. Evidence that the new use represents standard medical therapy might be obtained from a number of different sources. The preamble to the proposal set forth the following possible considerations: (1) Whether the new use meets the requirements of section 1861(t)(2)(B) of the Social Security Act, which defines ''medically accepted indications'' with respect to the use of a drug; (2) Whether a medical specialty society that is represented in or recognized by the Council of Medical Specialty Societies (or is a subspecialty of such society) or is recognized by the American Osteopathic Association has found that the new use is consistent with sound medical practice; (3) Whether the new use is described in a recommendation or medical practice guideline of a Federal health agency, including the National Institutes of Health, the Agency for Health Care Policy and Research, and the Centers for Disease Control and Prevention of the Department of Health and Human Services; and (4) Whether the new use is described in a current compendia such as the United States Pharmacopoeia Drug Information for the Health Care Professional, the American Medical Association Drug Evaluations, or the American Hospital Formulary Service (see 63 FR 31143 at 31150).

74. A number of comments objected to FDA's proposed criteria for the unethical exemption—particularly the emphasis on the requirement that it ordinarily would arise only in situations in which the new use appears to affect mortality or irreversible morbidity. Some comments believed that the criteria set forth in the legislative history (that are discussed in the preamble) should be in the codified language. Finally, a number of comments argued that if the new use is the standard of medical care, FDA must automatically grant an exemption.

The act clearly does not require FDA to automatically grant an exemption if a new use is the standard of medical care. The act says that FDA must *consider (among other considerations that the Secretary finds appropriate*) whether the new use is the standard of medical care, and that is what FDA proposed to do. Moreover, an automatic exemption would not be reasonable from a scientific standpoint because there are many instances in which the results of a controlled clinical trial have demonstrated that a drug or device is unsafe or ineffective for a new use for which it is considered to be the standard of care.

The standard set forth in § 99.205 is consistent with how FDA determines what studies are unethical in other contexts (i.e., when a manufacturer argues that it would be unethical to conduct a study). Moreover, the standard is consistent with the legislative history, which provides that such exemptions should be granted in limited circumstances. Therefore, FDA is retaining the proposed basic standard for the unethical exemption in the final rule (i.e., the data are persuasive to the extent that withholding the drug or device in the course of conducting a controlled study would pose an unreasonable risk of harm to human subjects). FDA continues to believe an effect on irreversible morbidity or mortality is what ordinarily would be required to show an unreasonable risk of harm. Nevertheless, there could be other circumstances in which the agency would find that it would be unethical to do the study, i.e., because there would be an unreasonable risk of harm even though the new use does not affect irreversible morbidity or mortality. In making a determination that it would be unethical to conduct a study, the agency must consider whether informed consent and proper IRB review would address the concerns raised by questions about whether it is appropriate to conduct a study.

FDA rejects the suggestion that the factors set forth in the legislative history that FDA may consider in deciding whether to grant an exemption be included as requirements in the codified language. FDA has included the statutory factors in the codified language. The legislative history provides that FDA may consider those factors among other factors, and thus, consideration of these factors is neither mandatory nor is it exclusive.

75. One comment argued that the standard needs to take into account the difficulty of enrolling patients in a study in which some subjects will receive a placebo when a patient can go to a doctor and receive a prescription for the drug. The comment further noted that physicians refuse to participate in placebo controlled studies of therapies they already believe to be effective.

FDA agrees that it can be difficult to enroll patients in placebo controlled trials and that this could be a relevant consideration. Moreover, not all controlled studies are placebo controlled. Companies may be able to conduct studies of a different design, depending on the situation. For example, a company may be able to compare the new use to another therapy that is known to work or may be able to rely on historical controls. In some cases, the new use could be added to existing therapy and compared with placebo added to existing therapy. If these alternate study designs mean that the study or studies will take longer, FDA can consider whether to extend the time to conduct the studies and submit a supplemental application.

76. One comment suggested that FDA should grant an exemption if the new use is listed in the USP DI or Hospital Formulary. Another comment suggested that an unethical exemption should be granted if the unapproved use: (1) Is accepted in a monograph of the USP; (2) is approved by another ''first world'' country; or (3) is approved by a state FDA. Finally, one comment suggested that FDA should automatically grant an unethical exemption if the new use: (1) Represents the standard of care, as represented by inclusion in specified compendia or practice guidelines, or (2) involves a combination of products or more than one sponsor and should grant other exemptions on a case-by-case basis.

FDA does not agree that any of these individual factors is enough to show that studying a new use would be unethical. Moreover, there is nothing in the statute or legislative history to

suggest that any of the single factors should be sufficient to meet the unethical exemption. FDA will, however, consider these factors in making its determination of when it would be unethical to conduct a study.

77. One comment noted that, although it supported the list of sources to be used to provide evidence that a new use represents standard medical therapy, after 1998, the American Medical Association's (AMA's) Drug Evaluation and the USP DI may no longer be available.

If the AMA's Drug Evaluation and/or the USP DI become unavailable, FDA will stop using them as evidence that a new use is the standard of care.

78. One comment noted that there are diverse opinions in the medical community about what standard of care means. Another noted that ''consistent with sound medical practice'' is not the same as ''standard of care'' and that an unapproved treatment may be considered to be sound medical practice but should still be studied. Several comments noted that FDA should take care in how it interprets ''standard medical treatment or therapy.'' These comments noted that manufacturers should not be allowed to take advantage of a situation of their own creation. In other words, standard medical treatment should not be interpreted as meaning treatment that is regularly used because physicians have no other choice because to do so would eliminate the requirements for completing any pediatric research.

FDA agrees that just because a certain treatment is consistent with sound medical practice does not mean that it is the standard of care. FDA has stated that whether a medical specialty society that is represented in or recognized by the Council of Medical Specialty Societies (or is a subspecialty of such society) or is recognized by the American Osteopathic Association has found that a new use is consistent with sound medical practice will be considered as evidence that it is the standard of care. Moreover, just because an unapproved use of a drug or device is the standard of care, does not mean that it is automatically exempt from the requirement to conduct the study needed to submit a supplemental application.

79. Several comments noted that it is almost inconceivable that the study of a new use for children could be viewed as unethical.

FDA will make this determination on a case-by-case basis.

80. Several comments argued for making the exemption process public. One comment said that all information should be made public as soon as a manufacturer requests an exemption and that if an exemption is granted all information should remain in the public domain so that interested parties will be able to play a role in keeping FDA informed as to when it should be revoked. Another suggested that prior to granting any exemption, FDA should hold a meeting of the appropriate advisory committee so that the public has the opportunity to review and comment upon the request.

As set forth previously, FDA declines to adopt a notice and comment process for considering exemption requests. The information will be made available to the public consistent with FOIA and FDA's regulations. FDA has the option of consulting advisory committees about exemption requests, when appropriate.

4. Subpart D—FDA Action on Submissions, Requests, and Applications

a. Agency action on a submission (§ 99.301). Proposed § 99.301 described the range of FDA's actions when it receives a submission. For example, under the proposal, FDA could determine that a manufacturer's submission does not comply with the regulatory requirements, request additional information or documents to assist the agency in determining whether the information to be disseminated complies with applicable requirements, or determine that the information fails to provide data, analyses, or other written matter that is objective and balanced. The proposal also described FDA actions in response to a manufacturer's submission when the manufacturer is committing to submit a supplement on completed studies or is agreeing to conduct the necessary studies and then submit a supplement.

81. Proposed § 99.301(a) provided that, within 60 days, FDA may determine that a submission does not comply with the requirements of the proposal or that it needs more information. A number of comments objected to the proposal because they believed that FDA would use it to extend the 60-day time period. The concern was that FDA would, on day 59, advise a manufacturer that their submission was not complete and therefore the 60-day time period had not begun. The comments said that Congress meant for FDA to give a final answer within the 60-day time period. Some comments argued that FDA should let manufacturers know if their submission is complete within a short period of time, e.g., within 15 days of receiving the submission.

In response to these comments, FDA has eliminated proposed § 99.301(a)(2) so that manufacturers will have a final decision within 60 days. Within the 60-day period, FDA will either notify a manufacturer that it has not met the requirements set forth in the law or allow the dissemination to go forward. FDA is not adopting the comment's suggestion that it advise sponsors as to whether their submissions are complete within a certain number of days (e.g., 15). The 60-day statutory timeframe is too short for the agency to make a commitment to provide such advice.

82. One comment stated that FDA should be required to notify the manufacturer promptly if it approves a submission in less than 60 days.

There is no requirement in the statute that FDA notify a manufacturer unless it intends to stop the dissemination of information under this part. Therefore, FDA is not revising the regulation as suggested. The agency will, however, make an effort to notify manufacturers promptly if it approves a submission in less than 60 days.

83. One comment requested that FDA change the ''may'' in proposed § 99.301(a) to ''shall'' and to clarify that a sponsor may begin to disseminate material if it has not heard from FDA within 60 days. Another comment suggested that FDA clarify § 99.301 to indicate that FDA will review an IND or IDE and will notify the manufacturer of the IND or IDE approval and that, until such notification, the manufacturer cannot disseminate the information.

FDA declines to change the ''may'' to ''shall'' in § 99.301(a). FDA is not required to do any of the things listed in § 99.301(a), and so use of the word ''shall'' would be inappropriate. Moreover, it is not true that a manufacturer may, in every circumstance, begin dissemination if it has not heard from FDA within 60 days. Under section 554(c) of the act, a manufacturer that has certified that it will conduct the studies needed to submit a supplement and that has submitted a proposed protocol and schedule for conducting such studies cannot disseminate unless the Secretary has determined that the proposed protocol is adequate and that the schedule for completing the studies is reasonable. Nevertheless, FDA has revised § 99.301(b) to state clearly that the agency will make a positive or negative determination on the manufacturer's protocols (and, where appropriate, its schedules) within 60 days after receiving a submission under part 99.

84. Proposed § 99.301(a)(3) (now redesignated as § 99.301(a)(2)) provided

that FDA shall provide a manufacturer notice and an opportunity for a meeting regarding the agency's determination that the information submitted is not objective and balanced, and requires additional information. One comment suggested that there should be a specific timeline for when such a meeting would occur.

The statute does not require that FDA set a timeline for such a meeting. Nevertheless, FDA will provide for such an opportunity as soon as is mutually convenient for FDA and the manufacturer. In any event, the meeting will take place within the 60-day period. Furthermore, should FDA determine that additional articles are necessary to provide objectivity and balance, the agency will apply the same standards for scientific soundness to those additional articles.

85. Proposed § 99.301(a)(4) (now redesignated as § 99.301(a)(3)) provided that within 60 days of receiving a manufacturer's submission, FDA may require the manufacturer to maintain records that will identify individual recipients of the information that is to be disseminated.

Some comments supported FDA's not requiring individualized recordkeeping in all situations. Others, however, thought it should be invoked in all situations and still others thought that ever requiring it was too burdensome. One comment argued that the proposed standard for individual recordkeeping was too vague and suggested that FDA make such a request ''only in rare circumstances, when warranted because of special safety considerations associated with a new use.'' One comment argued that FDA should provide notice and an opportunity to meet in the event that it requires a company to maintain records identifying individual recipients.

Section 553(b) of the act (21 U.S.C. 360aaa-2(b)) expressly requires a manufacturer to keep records that the manufacturer may use if it is required to take corrective action. Section 553(b) of the act also states that, ''Such records, at the Secretary's discretion, may identify the recipient of information provided * * * or the categories of such recipients.'' FDA does not believe that it would be appropriate to require individual recordkeeping in all circumstances. Similarly, FDA does not believe that it would be appropriate to require recordkeeping of categories of recipients in all circumstances. FDA agrees, however, that it should better define the standard for individual recordkeeping and will adopt, with slight modifications, the standard suggested by the comments. Section 99.301(a)(3) provides for individual recordkeeping when warranted because of special safety considerations associated with the new use. FDA did not adopt the ''only in rare circumstances'' language because although it expects to require this in limited circumstances, it does not yet have experience implementing this provision and nothing in the statute or legislative history indicates that Congress intended it to be rare.

86. One comment was concerned that because the agency has to review all submissions within 60 days, sometimes the timeframe will expire and allow information dissemination or exemptions to happen without agency review and thus patients could be harmed before FDA has time to terminate a deemed approval. This comment encouraged the agency to provide information to health care providers on the process by which the review will occur.

FDA recognizes that the act would allow information to be disseminated without agency review. The agency is committed to reviewing all of this information so that inappropriate information does not get disseminated.

87. Proposed § 99.301(b) required FDA to notify the manufacturer if the agency determines that its protocol and schedule for conducting studies are adequate and reasonable. Until FDA provides such notification, dissemination cannot begin. One comment noted that it was not the intent of Congress that the 60-day timeframe be delayed as a result of ongoing IND/IDE negotiations.

The statute provides that a manufacturer who submits a protocol and proposed schedule for conducting the studies needed to submit a supplement, cannot begin to disseminate until FDA determines that they are adequate. (See section 554(c)(1) of the act.) However, as stated earlier, FDA has revised § 99.301(b) to state that the agency will make a positive or negative determination on the manufacturer's protocols (and, where appropriate, its schedules) within 60 days after receiving a submission under 21 CFR part 99.

88. Proposed § 99.301(b) described FDA action on a manufacturer's proposed protocols and schedules for completing studies. One comment said that the rule should clarify which functional groups within FDA will be responsible for the review of protocols and studies and provide for a timeline for such review.

FDA has stated previously that clinical information, including protocols, that is submitted under this part will be reviewed by the appropriate review divisions. It is not necessary for the rule to detail FDA's internal procedure. FDA will review such protocols and schedules within 60 days. Section 99.301(b) includes that timeframe.

89. Under proposed § 99.301(b)(2), if a manufacturer has completed studies that it believes would be an adequate basis for the submission of a supplemental application for the new use and has certified that it will submit such supplement within 6 months, FDA would conduct a preliminary review of the study reports to determine whether the studies are potentially adequate to support the filing of a supplemental application for the new use. If FDA determines that the study reports are inadequate to support the filing of a supplemental application for the new use or are not complete, FDA will notify the manufacturer and the manufacturer shall not disseminate the new use information under this subpart. One comment argued that FDA should not be allowed to take a ''sneak peek'' at preliminary clinical trial data prior to its submission in a supplemental application.

Section 99.201(a)(4)(i) requires manufacturers that have completed studies that they believe would be an adequate basis for the submission of a supplemental application for the new use and have certified that it will submit such supplement within 6 months to submit the protocols for those studies. FDA, will, as in the case of the 36-month certification, review those protocols to determine whether they are adequate. The final rule has been revised to indicate that FDA will review the protocols submitted and not the study reports. However, this does not in any way affect the agency's ability to determine, based on information it has, including information about clinical trials, that the information a manufacturer seeks to disseminate is false or misleading or would pose a significant risk to public health.

b. Extension of time for completing planned studies (§ 99.303). Proposed § 99.303 described FDA's ability to: (1) On its own initiative, allow a manufacturer more than 36 months to submit a supplemental application, based on the review of the protocols(s) and planned schedule; or (2) grant a manufacturer's request to extend the 36-month period (for up to 24 months). Proposed § 99.303(a) described FDA's ability to determine, on its own initiative and before any studies have begun, that a manufacturer needs more than 36 months to complete the studies needed for submission of a

supplemental application and to submit such application. Proposed § 99.303(b) and (c) described FDA's ability, after such studies have begun and the sponsor has submitted a request, to grant an extension of the time to submit a supplement by up to 24 months. FDA would grant such an extension if the manufacturer makes a request for an extension in writing and FDA determines that the manufacturer has acted with due diligence to conduct the studies needed for the submission of a supplemental application for a new use and to submit such a supplemental application, but still needs more time.

90. The comments to this provision indicated that there was some confusion regarding these two different procedures. Several comments asked FDA to more clearly set out the two procedures contemplated by the statute. Several comments asked FDA to make clear that the 24-month limitation applies only to an extension request made after a study has begun. One comment suggested that there could be more than one 24-month extension.

FDA has revised this section to make clear that there are two different types of extensions. The first extension (in § 99.303 (a)) relates to FDA's ability to determine, with or without a request from the manufacturer, that 36 months is not enough time to complete a study of the new use and submit a supplemental application. This would occur before any studies are begun, either before the submission is made or at the time of the submission. There is no limit on how much time FDA may give a manufacturer under this subsection.

The second type of extension (described in revised § 99.303(b)) relates to FDA's ability to grant a manufacturer's request for an extension after a study has begun because, even though it appeared that 36 months would be sufficient and the manufacturer has acted with due diligence, the manufacturer has run into problems and needs more time. This type of extension is limited to 24 months and the statute does not provide that FDA can give more than one 24-month extension.

c. Exemption from the requirement to file a supplemental application (§ 99.305). Proposed § 99.305 described FDA action on a request for an exemption from the requirement to submit a supplemental application and the criteria to be considered in deciding whether to grant a request for an exemption, either because it would be economically prohibitive to conduct the studies needed for a supplemental application or it would be unethical to conduct the clinical studies needed to approve the new use.

91. Proposed § 99.305(a)(1) states that FDA must act on an application for an exemption within 60 days of receipt or it will be deemed approved. However, under proposed § 99.305(a)(2), FDA could, at any time, terminate such deemed approval if it determines that the requirements for granting an exemption have not been met. One comment noted that FDA can terminate such deemed approval only if a manufacturer is disseminating information under section 551 of the act.

Section 554(d)(3)(B) of the act provides that if a manufacturer disseminates information under section 551 of the act under a deemed approval of a request for an exemption, FDA may, at any time, terminate a deemed approval and order the manufacturer to cease disseminating the information under section 553(b)(3) of the act. FDA does not believe that it has to wait for a manufacturer to actually disseminate information in order to terminate the deemed approval.

92. A number of comments suggested that FDA provide a manufacturer an opportunity to meet concerning: (1) FDA's determination that the manufacturer cannot disseminate information under this part; (2) FDA's determination that the manufacturer should maintain records of individual recipients; (3) FDA's determination of a company's request for an extension of time to complete the necessary studies and submit a supplement; (4) FDA's denial of an exemption.

Section 401 of FDAMA directed FDA to provide manufacturers an opportunity to meet regarding a determination that the information to be disseminated is not balanced and objective and regarding the cessation of information dissemination in certain circumstances. The statute does not direct FDA to meet in the circumstances described previously. Nevertheless, as always, FDA will honor requests for meetings to the fullest extent feasible. Given the short timeframes set forth in section 401 of FDAMA, FDA's resource constraints, and the fact that FDA does not know how many submissions it will receive under this part, FDA is not imposing on itself any additional requirements for meetings by making those meetings a part of the regulation.

5. Subpart E—Corrective Actions and Cessation of Dissemination

Subpart E, as proposed, contained provisions describing the corrective actions that FDA could take or order the manufacturer to take, termination of approvals of applications for exemption, and the applicability of labeling, adulteration, and misbranding authority in the event that dissemination failed to comply with section 551 of the act.

93. One comment claimed that proposed subpart E was ''hollow and meaningless'' because Congress did not give FDA the authority to seek civil money penalties against noncomplying manufacturers.

FDA disagrees with the comment's characterization of subpart E and notes that the agency does, indeed, have the authority to seek civil money penalties from any person who violates most requirements of the act pertaining to devices (see section 303(f) of the act (21 U.S.C. 333(f)). Additionally, arguments regarding other civil money penalty authority for violations of these regulations are beyond the scope of this rulemaking.

a. Corrective actions and cessation of dissemination of information (§ 99.401). Proposed § 99.401 authorized FDA to take corrective actions and to order a manufacturer to cease dissemination of information and take corrective action. In general, the proposal would provide for corrective action or an order to cease dissemination of information based on post dissemination data, information disseminated by the manufacturer, or the manufacturer's supplemental application for the new use (or its failure to submit or to complete the studies necessary for the supplemental application). Proposed § 99.401 also described the procedures to be observed, such as consultation with the manufacturer, notice regarding FDA's intent to issue an order to cease dissemination, and opportunities for a meeting, and described when a manufacturer shall cease disseminating information in the event of its noncompliance with the regulations.

94. Several comments would revise proposed § 99.401 to give manufacturers a mechanism for appealing the agency's decision to require corrective action. The comments would either amend the rule to refer to the dispute resolution provision at section 562 of the act (21 U.S.C. 360bbb-1), the regulations for internal agency review of decisions (§ 10.75 (21 CFR 10.75)), or other appeals processes.

FDA declines to revise the rule to refer to statutory or regulatory appeals mechanisms. Such appeals mechanisms are available regardless of whether § 99.401 refers to them or not, and it would be both impractical and unnecessary to list all possible statutory and regulatory appeals mechanisms in § 99.401. Moreover, such a list would either become obsolete or useless if any

statutory or regulatory citations for the appeals mechanisms changed or would require FDA to monitor constantly all cross-references without any appreciable benefit.

95. Several comments would amend § 99.401 to permit manufacturers to continue disseminating information pending the outcome of any appeal except where a significant safety issue or public health concern exists. In contrast, one comment said that a manufacturer should cease disseminating information while it and FDA are resolving any outstanding issues. FDA declines to revise the rule to allow manufacturers to continue disseminating information pending the outcome of any appeal. In general, section 555 of the act (21 U.S.C. 360aaa-4) authorizes the agency to order a manufacturer to cease dissemination of information on the unapproved/new use; it does not require the agency to stay or defer the effectiveness of such an order pending any appeal by the manufacturer. This outcome is consistent with the appeals or dispute resolution provisions cited by the comments (section 562 of the act and § 10.75), as well as other regulatory mechanisms for requesting reconsideration (see, e.g., 21 CFR 10.33 (administrative reconsideration of action) and 21 CFR 10.35 (administrative stay of action)); none of these mechanisms results in an automatic stay of agency action while the agency reconsiders its decision or considers an appeal.

96. One comment suggested that FDA define ''appropriate corrective action.'' The comment would amend the rule to give examples of corrective action and to describe the circumstances under which specific corrective actions might apply.

By using the term ''appropriate corrective action,'' FDA meant to give itself the flexibility to fashion the corrective action to remedy the underlying problem or deficiency. As stated in the preamble to the proposed rule, these actions include, but are not limited to, ordering the manufacturer to send ''Dear Doctor'' letters, to publish corrective advertising, to include warning labels on the product, or to include warnings or otherwise revise the product labeling (63 FR 31143 at 31151). FDA declines to define ''appropriate corrective action'' or to give examples and to specify when it might order a manufacturer to take a particular corrective action. The agency's regulatory experience indicates that regulations containing lists or examples often are misconstrued as providing an exclusive list (thereby resulting in unnecessary disputes as to whether a particular corrective action is within the regulation or whether the manufacturer's action is even capable of being addressed by the agency) and that regulations that describe specific responses to specific situations can deprive the agency of the flexibility to tailor a corrective action to fit a particular situation. Nevertheless, FDA would note that it expects that ''Dear Doctor'' letters and/or corrective advertising would be used much more often than the addition of warning statements or product labeling, which are likely to be used in the more extreme cases.

97. Proposed § 99.401(a) permitted FDA to take appropriate action to protect the public health, including ordering a manufacturer to cease dissemination and take corrective action, if FDA determines, based on data received after the dissemination has begun, that the new use that is the subject of the disseminated information may not be effective or may pose a significant risk to public health. The provision required FDA to consult with the manufacturer before taking any such action.

One comment disagreed that FDA should have any obligation to consult a manufacturer before ordering the manufacturer to cease disseminating information on an unapproved/new use.

Section 555(a)(1) of the act, regarding corrective actions following the receipt of data after a manufacturer has begun disseminating information, expressly states that the agency, ''after consultation with the manufacturer,'' shall take ''such action regarding the dissemination of the information as [the agency] determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer to cease dissemination of the information.'' Thus, with respect to corrective actions based on post-dissemination data, the act requires FDA to consult the manufacturer before taking any action, and § 99.401(a) correctly reflects this statutory requirement.

98. FDA revised § 99.401(c)(3) and (c)(4), by changing the references to § 99.303 from paragraphs (a) or (c) to paragraphs (a) or (b). This change was needed to correct an error and to reflect the changes made to § 99.303, which were previously discussed.

99. Proposed § 99.401(b) discussed FDA's ability to order cessation of dissemination or corrective action because the information being disseminated by a manufacturer does not comply with part 99. Proposed § 99.401(b)(1) directed FDA to give a manufacturer the opportunity to bring itself into compliance if the manufacturer's noncompliance constituted a minor violation. Proposed § 99.401(b)(2) permitted FDA to order the manufacturer to cease dissemination of information after providing notice to the manufacturer and an opportunity for a meeting.

One comment would revise § 99.401(b)(2) to specify a timeframe for a meeting, but did not explain why such specificity would be beneficial.

FDA declines to revise the rule as suggested by the comment. Because FDA cannot require a manufacturer to cease dissemination until it has provided an opportunity for a meeting, it has an incentive to schedule such meetings at the earliest possible time, particularly when the new use at issue raises significant safety concerns. By not specifying a timeframe for a meeting, the regulation provides the appropriate flexibility to schedule meetings.

100. One comment said that FDA should afford manufacturers an opportunity to resolve outstanding issues before taking any corrective action to avoid burdensome and erroneous corrective action.

Section 555(b)(1) of the act requires FDA to delay issuing an order to provide a manufacturer an opportunity to correct a minor violation before ordering such manufacturer to cease dissemination. Section 99.401(b) provides that opportunity. Moreover, FDA will always consider whether and when corrective action is appropriate.

101. Proposed § 99.401(c) described FDA actions based on a manufacturer's supplemental application. For example, under proposed § 99.401(c)(1), FDA could order a manufacturer to cease dissemination and to take corrective action if the agency determined that the supplemental application does not contain adequate information for approval of the new use.

One comment said that FDA should not automatically require a manufacturer to cease dissemination if FDA does not approve a supplemental application for the unapproved/new use because it fails to establish effectiveness. The comment said corrective action should be reserved for situations in which ''some significant public health concern is identified that would be materially addressed by such corrective action.''

FDA declines to revise § 99.401(c) to limit corrective actions as suggested by the comment. If FDA, based on the supplemental application submitted by the manufacturer, determines that the drug or device is not effective for that use, it could be contrary to the interests

of public health to allow the manufacturer to continue disseminating information on that use. Section 555(b)(2) of the act contemplates such a result by stating that the agency may order a manufacturer to cease dissemination if the agency determines that the supplemental application does not contain adequate information for approval of the new use.

Furthermore, one should note that both section 555(b)(2) of the act and § 99.401(c) give FDA discretion in issuing an order to cease dissemination of information on the unapproved/new use if FDA does not approve the supplemental application. Thus, contrary to the comment's assertion, an order to cease dissemination under such circumstances is not ''automatic.''

102. One comment said that if FDA does not approve a supplemental application because the studies failed to demonstrate efficacy, the manufacturer should advise health care practitioners who previously received information on the unapproved/new use.

Requiring a manufacturer to notify recipients or categories of recipients that a drug or device is not effective for the unapproved/new use would be within the range of corrective actions that FDA may take. Section 553(b) of the act contemplates such a result by requiring manufacturers to keep records of categories of recipients or individual recipients of the disseminated information and to use such records if the manufacturer is required to take corrective action. Thus, corrective actions, in § 99.401, are not confined to orders to cease dissemination of information on an unapproved/new use.

103. One comment sought clarification as to when FDA may determine that a supplemental application does not contain adequate information for approval of the new use. The comment suggested that proposed § 99.401(c)(1) could be interpreted as applying even if FDA requested additional information or clarification of a supplemental application. The comment stated that dissemination of information on an unapproved/new use should cease only when FDA determines that the supplemental application is not approvable.

Section 555(b)(2) of the act permits FDA to order a manufacturer to cease dissemination if FDA determines that a supplemental application submitted by such manufacturer (for the new use) does not contain adequate information for approval of the new use. Section 99.401(c)(1) tracks this language. FDA agrees that a decision to seek additional data or clarification regarding a supplemental application would generally not constitute a determination that the supplement does not contain adequate information for approval of the new use. However, there may be circumstances in which it is appropriate for the agency to order a manufacturer to cease dissemination of information when additional data is required. Accordingly, FDA will make these determinations on a case-by-case basis.

104. Proposed § 99.401(c)(2) permitted FDA to order a manufacturer to cease dissemination if the manufacturer had certified that it would submit a supplemental application within 6 months, and the manufacturer failed to submit a supplemental application within 6 months.

One comment said FDA should not seek corrective action for a manufacturer's failure to submit a supplemental application within 6 months if there is ''good cause'' for the delay. The comment said that FDA should meet with a manufacturer to determine if there is good cause for the delay before automatically requiring corrective action and that manufacturers should notify FDA as soon as possible if they will not meet any deadline.

FDA declines to revise the rule as requested by the comment. Section 99.401(c)(2) does not require any specific corrective action in the event that the manufacturer fails to submit a supplemental application on time. Instead, it gives FDA the discretion to order the manufacturer to cease dissemination of information and to take corrective action. FDA will consider, among other things, the reasons for a manufacturer's inability to submit a supplemental application on time when deciding what type of corrective action to take or whether any corrective action is needed.

Thus, while FDA would appreciate any advance notice from manufacturers who believe that they will be unable to submit a supplemental application on time and will meet with manufacturers as time and resources permit, given the agency's discretion regarding corrective actions in § 99.401(c)(2), revising the rule to require such meetings is unnecessary.

105. Proposed § 99.401(d) considered an order to cease dissemination of information to be effective upon the date of issuance unless otherwise stated by FDA.

One comment said it would be more efficient if an order to cease dissemination of information were effective upon date of receipt by the manufacturer. The comment explained that a manufacturer may be unaware when FDA issues an order to cease dissemination of information, so the order should be effective when the manufacturer receives it. The comment also stated that it would be unlikely that a manufacturer could stop dissemination of information throughout the United States on the same day it receives an order to cease dissemination. Consequently, the comment would revise the rule to give manufacturers some time (the comment suggested 60 days) in which to comply with the order.

FDA agrees, in part, with the comment and has revised § 99.401(d) to make an order to cease dissemination of information effective upon receipt by the manufacturer, unless otherwise indicated in the order. The agency does not agree that manufacturers should have a specified amount of time after receipt to comply with an order. A manufacturer is expected to comply immediately. If the manufacturer is unable to comply immediately, it should notify FDA, and FDA will evaluate the situation on a case-by-case basis.

106. Proposed § 99.401(e) required a manufacturer to cease dissemination if it fails to comply with the regulations pertaining to dissemination of information on unapproved/new uses. This would include discontinuation, termination, and a failure to conduct with due diligence clinical studies. The proposal also required the manufacturer to notify FDA if it ceases dissemination under § 99.401(e).

One comment would revise the rule to require a manufacturer to notify FDA of any failure to comply as soon as the manufacturer realizes the failure and ceases dissemination. The comment also would require the manufacturer to notify FDA immediately if the manufacturer ceases dissemination. Section 99.401(e) already requires a manufacturer to notify FDA if it ceases dissemination.

FDA agrees that the agency should be notified immediately and has revised § 99.401(e) accordingly.

b. Termination of approvals of applications for exemption (§ 99.403). Under the act, if FDA fails to act within 60 days on an application for an exemption from the requirement to file a supplemental application, the application is deemed approved. Proposed § 99.403 allowed FDA to terminate the deemed approval of an application for an exemption if FDA determines that the manufacturer has failed to meet the requirements for granting an exemption. In addition, the agency may order the manufacturer to cease disseminating information about the new use and, if appropriate, to take corrective action.

107. One comment would revise § 99.403(a)(3) to apply if FDA determines that it would be economically *and* ethically possible to conduct the studies needed for a supplement rather than economically *or* ethically possible to conduct such studies.

FDA agrees and has revised the rule accordingly.

108. One comment requested that FDA provide notice and an opportunity to meet when FDA terminates approval of an application for an exemption.

Section 99.403(c), (d), and (e) provide for notice to the manufacturer, and § 99.403(d) also mentions consultation between FDA and the manufacturer if FDA determines that the manufacturer no longer meets the requirements for an exemption on the basis that it is economically prohibitive or unethical to conduct the studies needed to support a supplemental application for the new use. Thus, no further change to the rule is necessary.

c. Applicability of labeling, adulteration, and misbranding authority (§ 99.405). Proposed § 99.405 provided that the dissemination of information about a new use could constitute labeling, evidence of a new intended use, adulteration or misbranding of the product if it fails to comply with the requirements in section 551 of the act and the requirements of this part.

109. One comment claimed that proposed § 99.405 was too broad and exceeded the statute by considering a failure to comply with part 99 to constitute labeling, evidence of a new intended use, adulteration, or misbranding of a drug or device. The comment acknowledged that labeling that is false or misleading renders a drug misbranded and that each introduction of the drug into interstate commerce constitutes a separate prohibited act under section 301 of the act (21 U.S.C. 331). The comment further acknowledged that FDA can pursue various enforcement actions, such as seizures, injunctions, and criminal penalties, for each prohibited act. However, the comment argued that a failure to comply with part 99 should be a single violation rather than a violation for each product sold and that if a manufacturer tries to follow part 99, the act prescribes specific enforcement consequences, such as corrective action, before FDA resorts to other sanctions.

FDA disagrees with this comment. Although section 401 of FDAMA provided FDA additional enforcement tools for violative dissemination of off-label information, it did not in any way eliminate or limit FDA's ability to use its already existing enforcement mechanisms.

6. Subpart F—Recordkeeping and Reports

Recordkeeping and reports (§ 99.501). Proposed § 99.501 required a manufacturer that disseminates information under part 99 to maintain records sufficient to allow it to take corrective action that is required by FDA and described some of the records to be kept. The proposal gave manufacturers the option of maintaining records that identify recipients of the disseminated information by name or by category, but would require manufacturers who choose to identify recipients by category to ensure that any corrective action FDA requires will be sufficiently conspicuous so as to reach the individuals who have received the information about the new use. The proposal also permitted FDA to require manufacturers to keep records identifying recipients by name and required a manufacturer to keep records for 3 years after it has ceased disseminating the information on an unapproved or new use and to make the records available to FDA for inspection and copying.

110. One comment suggested that FDA permit manufacturers to submit reports via the Internet. The comment said that this would reduce paperwork burdens and provide a continuous source of current information.

FDA currently receives certain submissions from industry in electronic form and encourages increased utilization of this means. Initiatives are underway to formalize a process for electronic submission.

111. Several comments focused on proposed § 99.501(a)(1)(i), which required records to identify, by name, the persons receiving the disseminated information. This provision would apply if the manufacturer did not keep records identifying recipients by category or if FDA required the manufacturer to keep records identifying recipients by name. One comment supported the provision as written. Several comments would amend the rule to require manufacturers to keep records identifying recipients by name in all cases. These comments explained that requiring manufacturers to maintain records of specific recipients would help ensure timely action or notification if the new use is ineffective or presents a significant risk to the public health. The comments said such records also would help ensure that the manufacturer disseminated the information to the appropriate recipients. Two comments suggested requiring manufacturers to keep records of health professionals by name, health plans, and pharmacies that receive information in cases of a recall.

In contrast, several comments objected to ever requiring manufacturers to identify recipients by name. Some comments acknowledged that section 553(b) of the act ''technically'' gives FDA the discretion to require such records, but nevertheless said the provision was ''unnecessary'' or ''unduly burdensome.'' These comments would delete the requirement and only require manufacturers to maintain records identifying recipients by category.

FDA declines to revise the rule as suggested by the comments. Section 553(b) of the act expressly requires a manufacturer to keep records that the manufacturer may use if it is required to take corrective action. Section 553(b) of the act also states that, ''Such records, at the Secretary's discretion, may identify the recipient of the information provided * * * or the categories of such recipients.'' To require manufacturers to keep records identifying the recipients in all cases, or in no cases, as suggested by the comments, would be contrary to the express terms in section 553(b) of the act. As previously discussed, however, FDA has better defined the standard for individual recordkeeping. Section 99.301(a)(3) of the final rule provides for individual recordkeeping when warranted because of special safety considerations associated with the new use.

112. One comment claimed that proposed § 99.501(a)(1)(i) exceeded the statutory requirement. The comment said that if FDA requires a manufacturer to maintain records identifying recipients by category, then if corrective action is later required, FDA should not expect manufacturers to generate lists of individual recipients that are to receive such corrective action.

The comment misinterprets the rule. Under § 99.301(a)(3), when FDA reviews a manufacturer's submission, the agency would determine whether records identifying individual recipients must be kept. FDA would impose such a requirement in limited circumstances before the manufacturer disseminates any information on the unapproved/new use. Section 99.501(a)(1)(i) does not provide a new mechanism for requiring manufacturers to keep records identifying individual recipients nor does it contemplate requiring manufacturers not previously required to identify individual recipients to generate such records if corrective action becomes necessary.

113. Several comments discussed the semiannual submissions to FDA under proposed § 99.501(b). Several comments objected to proposed § 99.501(b)(3) and (b)(4), which required a notice and summary of any additional clinical research or other data relating to the safety or effectiveness of the new use and periodic progress reports on the manufacturer's studies. The comments stated that such reporting requirements would duplicate information that FDA already receives under existing reporting requirements for IND's and NDA's. One comment objected to the semiannual frequency of the reports. Another argued that FDA failed to set forth ''limits on the responsibilities'' of manufacturers ''as the Secretary deems appropriate'' regarding additional information that must be submitted. Finally, one comment asked FDA to acknowledge that these reports are exempt from disclosure under FOIA.

Section 99.501(b)(3) and (b)(4) reflect the statutory requirement at sections 555(a)(2) and 554(c)(2) of the act respectively. Section 555(a)(2) of the act states that, after a manufacturer disseminates information, the manufacturer shall submit ''a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved.'' Section 554(c)(2) of the act requires a manufacturer to submit periodic progress reports on its clinical studies. FDA drafted the proposed rule to have these periodic progress reports submitted on a semiannual basis in order to coincide with the reporting frequency for the lists of articles and categories of providers required by section 553(a) of the act. This would be more convenient for both manufacturers and the agency to have the reports and lists submitted at the same time. Thus, FDA did not intend to require duplicate reporting of information that is already submitted to the agency under other FDA regulations nor did FDA intend to make the submission of such reports burdensome.

To the extent that the information described in § 99.501(b)(3) and (b)(4) is already submitted to FDA as part of the routine reporting for an application for investigational use or for a marketing application, manufacturers may comply with § 99.501(b)(3) and (b)(4) by making a cross-reference to the relevant application for investigational use or for a marketing application. Thus, a manufacturer does not have to duplicate information that it has already submitted to FDA. Moreover, FDA did set limits on the manufacturers' responsibilities by requiring that the information be reported on a semiannual basis. Finally, as stated earlier, public disclosure of information submitted under this rule is dictated by the FOIA and FDA's regulations.

114. One comment sought clarification that a manufacturer must submit any additional article or publication to FDA before it can be disseminated. The concern was that manufacturers would interpret the semiannual filing requirement as sufficient once a manufacturer has received approval to disseminate information about a particular use.

The statute and regulation make clear that the manufacturer has to come to FDA before beginning to disseminate a journal article or reference publication that has not previously been submitted to FDA. In other words, once FDA has approved or passed on a specific journal article or reference text, the manufacturer can disseminate it to as many qualified recipients as it chooses, as long as the manufacturer continues to meet the requirements of this part. However, even if FDA has approved or passed on one journal article or reference publication for a new use, the manufacturer may not disseminate additional/different journal articles or reference publications for that same use without making a separate submission.

115. If a manufacturer received an exemption from the requirement to submit a supplemental application, proposed § 99.501(b)(5) would require the manufacturer to submit any new or additional information that relates to whether the manufacturer continues to meet the requirements for the exemption. One comment objected to this requirement, saying that it would need extensive market data to continue justifying the need for an exemption on economic grounds and that the cost of generating such information would itself be economically prohibitive.

FDA disagrees that it would be economically prohibitive to comply with this requirement. The regulation requires manufacturers only to provide new or additional information.

116. Proposed § 99.501(c) required a manufacturer to maintain a copy of all information, lists, records, and reports required or disseminated under part 99 for 3 years after it has ceased dissemination of such information and to make such documents available to FDA for inspection and copying. One comment requested clarification of this provision. The comment explained that if FDA approves the manufacturer's supplemental application, then the manufacturer would no longer be disseminating information on an unapproved/new use and would not be subject to part 99. Instead, any postapproval dissemination of information would be on an approved use and, therefore, would not be subject to the recordkeeping requirement in § 99.501(c).

The comment's interpretation of § 99.501(c) is correct. If FDA approves the manufacturer's supplemental application, the use is then ''approved'' and dissemination of information on the approved use would be outside the scope of part 99. However, documents relating to the dissemination of information before approval would remain subject to § 99.501.

7. Conforming Amendment to 21 CFR Part 16

The proposed rule would amend 21 CFR 16.1(b)(2) to add the due diligence determination under proposed § 99.401(c) to the list of regulatory actions that may be the subject of a part 16 hearing.

FDA received no comments on this provision and has finalized it without change.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages). Under the Regulatory Flexibility Act, unless an agency certifies that a rule will not have a significant economic impact on a substantial number of small entities, the agency must analyze regulatory options that would minimize the impact of the rule on small entities. Title II of the Unfunded Mandates Reform Act (Pub. L. 104–4) (in section 202) requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation).

The agency has reviewed this rule and has determined that it is consistent with the regulatory philosophy and principles identified in Executive Order 12866, and in these two statutes. Although this rule is not an economically significant regulatory action, it is still a significant regulatory action as defined by the Executive Order due to the novel policy issues it raises.

With respect to the Regulatory Flexibility Act, the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Because the final rule does not impose any mandates on State, local, or tribal governments, or the private sector that will result in a 1-year expenditure of $100 million or more, FDA is not required to perform a cost-benefit analysis under the Unfunded Mandates Reform Act.

The rule implements section 401 of FDAMA by describing the new use information that a manufacturer may disseminate and by setting forth procedures that manufacturers must follow before disseminating information on the new use. The benefits of the rule will derive from the public health gains associated with the earlier dissemination of objective, balanced, and accurate information on important unapproved uses of approved products. In addition, the rule may encourage new studies or the collection of evidence about these new uses.

The costs of the rule are modest. A firm would typically conduct clinical studies in support of a supplemental application for a new use only if the firm believed that the added revenues associated with the new indication would exceed the costs of the supporting studies. Because this rule will accelerate the receipt of these revenues, it is possible that some new use supplemental applications that would not have been economically justified in the absence of this rule, will now be submitted. No comments on the proposed rule attempted to project the magnitude of this incentive and FDA similarly could not estimate the number or cost of the additional clinical studies that might accompany these applications. The agency notes, however, that they would be undertaken voluntarily by the affected firms in the expectation that they would increase company profitability.

Manufacturers choosing not to disseminate new use information will incur no costs. Firms voluntarily choosing to disseminate new use information will experience added paperwork costs for each submission to the agency, but gain sales revenues from the information dissemination. FDA cannot make a precise estimate of the number of submissions that will be filed, but as explained in section V of this document, the agency tentatively forecasts that it will receive approximately 300 submissions each year from manufacturers for the purpose of disseminating new use information. FDA also estimates that the statutory and regulatory paperwork burdens associated with these submissions might total almost 52,000 hours, at an average labor cost of $35 per hour.[1] Thus, the total cost of the added paperwork is estimated to cost industry approximately $1.8 million per year. FDA received no public comments that specifically addressed its paperwork estimates.

The final rule should not have an adverse impact on any manufacturer. One comment asserted that the agency's definition of economically prohibitive implies that some manufacturers will disseminate information despite a resulting reduction in net income. The comment further indicated that this reduction in net income requires FDA to undertake additional analysis under the Regulatory Flexibility Act. The agency disagrees with this comment, because the final rule simply makes the dissemination of unapproved use information an option for those firms that find it beneficial to do so. Firms will compare the expected sales revenue from the new dissemination activity to the associated paperwork cost and disseminate the new information only if it increases their profitability. As noted previously, firms choosing not to disseminate new use information will face no increased costs. Because no firm is likely to experience a reduced net income, the rule will not have a significant adverse economic effect on a substantial number of small entities and no further analysis is required under the Regulatory Flexibility Act.

V. Paperwork Reduction Act of 1995

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given below in this section of the document with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA had submitted the information collection requirements for the proposed rule to OMB for its review. In its Notice of Office of Management and Budget Action, dated July 30, 1998, OMB stated that it had concerns regarding the burden and utility of the information collection that were to be ''assessed in light of public comments received.'' The terms of OMB clearance further stated that OMB:

> is particularly interested in determining whether the public has comments on the burden and utility of the information required to be included in a submission to FDA, including information submitted to meet the economically prohibitive' exception, and the three year recordkeeping requirement proposed in the rule. FDA shall specifically address any comments received on these and other issues related to the information collection requirements * * *.

The proposed rule provided an opportunity for public comment on the information collection requirements, but FDA received no comments that provided any contrary or different estimates. The agency did receive one comment declaring that the estimated information collection burden for the proposed rule ''may not be an accurate reflection of the actual burden,'' but the comment provided no data or further information that would enable FDA to revise the estimated information collection burden for the final rule.

The agency received several comments that questioned the utility of the information collection requirements. For example, several comments requested changes to the information that would be required to obtain an exemption when a manufacturer felt it would be ''economically prohibitive'' or ''unethical'' to conduct studies necessary to support a supplemental application. These comments generally stated that the proposed rule's criteria were too restrictive. The agency revised the ''economically prohibitive'' criteria in response to the comments and modified the language in the ''unethical'' exemption. These issues are discussed in more detail in the preamble to the final rule.

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[1] Updated from Eastern Research Group, Inc., ''Final Report—Economic Threshold and Regulatory Flexibility Assessment of Proposed Changes to the Current Good Manufacturing Practice Regulations for Manufacturing, Processing, Packaging, or Holding Drugs (21 CFR 210 and 211),'' March 13, 1995. Calculation allocates 50 percent of hours to middle management, 25 percent to upper management, and 25 percent to support staff.

discussed in more detail in the preamble to the final rule.

The agency did not receive any comments that questioned the utility of the 3-year recordkeeping requirement. One comment sought clarification as to whether the recordkeeping requirement would still apply if FDA approved the supplemental application for the new use, and FDA has addressed that comment in its discussion of the recordkeeping provision.

FDA did, however, simplify the provision concerning the ''economically prohibitive'' exception in response to comments it received. FDA discusses the impact of this revision on the estimated annual reporting burden later in this section.

FDA requested emergency processing of the information collection requirements for this final rule. OMB granted approval to the collection of information and assigned a control number (OMB 0910–0390). The final rule's information collection requirements, therefore, are effective upon November 20, 1998. However, the agency is also submitting the information collection requirements for the final rule to OMB for routine processing. Consequently, FDA is providing an opportunity for public comment on the final rule's information collection requirements.

FDA invites comments on: (1) Whether the collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Dissemination of Treatment Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices.

Description: The rule implements sections 551 through 557 of the act (21 U.S.C. 360aaa-360aaa-6) as amended by FDAMA, which requires a manufacturer that intends to disseminate certain treatment information on unapproved uses for a marketed drug, biologic, or device to submit that information to FDA. The rule sets forth the criteria and procedures for making such submissions. Under the rule, a submission would include a certification that the manufacturer has completed clinical studies necessary to submit a supplemental application to FDA for the new use and will submit the supplemental application within 6 months after dissemination of information can begin. If the manufacturer has planned, but not completed, such studies, the submission would include proposed protocols and a schedule for conducting the studies, as well as a certification that the manufacturer will complete the clinical studies and submit a supplemental application no later than 36 months after dissemination of information can begin. The rule also permits manufacturers to request extensions of the time period for completing a study and submitting a supplemental application and to request an exemption from the requirement to submit a supplemental application. The rule prescribes the timeframe within which the manufacturer shall maintain records that would enable it to take corrective action. The rule requires the manufacturer to submit lists pertaining to the disseminated articles and reference publications and the categories of persons (or individuals) receiving the information and to submit a notice and summary of any additional research or data (and a copy of the data) relating to the product's safety or effectiveness for the new use. The rule requires the manufacturer to maintain a copy of the information, lists, records, and reports for 3 years after it has ceased dissemination of the information and to make the documents available to FDA for inspection and copying.

Description of Respondents: All manufacturers (persons and businesses, including small businesses) of drugs, biologics, and device products.

The estimated burden associated with the information collection requirements for this rule is 52,208 hours.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
99.201(a)(1)	172	1.7	297	40	11,880
99.201(a)(2)	172	1.7	297	24	7,128
99.201(a)(3)	172	1.7	297	1	297
99.201(a)(4)(i)(A)	52	1.7	89	30	2,670
99.201(a)(4)(ii)(A)	52	1.7	89	60	5,340
99.201(a)(5)	52	1.7	89	1	89
99.201(b)	172	1.7	297	0.5	148.5
99.201(c)	172	1.7	297	0.5	148.5
99.203(a)	1	1.7	1	10	10
99.203(b)	1	1.7	1	10	10
99.203(c)	2	1	2	0.5	1
99.205(b)	17	1.8	30	82	2,460
99.501(b)(1)	172	3.4	594	8	4,752
99.501(b)(2)	172	3.4	594	1	594
99.501(b)(3)	172	3.4	594	20	11,880
99.501(b)(4)	2	1.7	3	2	6
99.501(b)(5)	17	1.8	30	41	1,230
Total Hours					48,644

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
99.501(a)(1)	172	1.7	297	10	2,970
99.501(a)(2)	172	1.7	297	1	297
99.501(c)	172	1.7	297	1	297
Total Hours					3,564

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA derived these estimates primarily from existing data on submissions made under supplemental applications and other submissions to the agency, as well as information from industry sources regarding similar or related reporting and recordkeeping burdens.

However, because the final rule revises the ''economically prohibitive'' exception requirement, FDA has decreased the estimated burden associated with an exemption request under § 99.205(b) and has increased the number of annual responses seeking an exemption. In the preamble to the proposed rule, FDA estimated that 1 percent or approximately 2 of the 172 manufacturers would submit an exemption request. The estimated reporting burden for § 99.205(b), as originally proposed, was 125 hours per response. This was based on a similar reporting burden for certain submissions under (§ 316.20 (21 CFR 316.20)) even though FDA stated that the actual reporting burden would probably be less because proposed § 99.205(b) was not as extensive as § 316.20. For the final rule, FDA has reduced the estimated reporting burden per response to 82 hours because the revised requirements are not as extensive as those in the proposal and has increased the total number of respondents and annual responses to 17 and 30 respectively (or approximately 10 percent of all respondents and submissions). This results in a total hour burden of 2,460 hours for § 99.205(b). Additionally, FDA has revised § 99.203 to permit manufacturers to request an extension of the 36-month time period for conducting studies and submitting a supplemental application before it makes a submission to FDA. FDA, therefore, has adjusted the information collection tables to reflect this revision.

The estimated increase in the number of exemption requests results in a corresponding decrease in the remaining number of submissions under § 99.201(a)(4)(i)(A), (a)(4)(ii)(A), and (a)(5). FDA assumes that the remaining 267 submissions will be divided equally among § 99.201(a)(4)(i)(A), (a)(4)(ii)(A), and (a)(5) resulting in 89 responses in each provision and approximately 52 respondents per provision. Although FDA has not altered the estimated burden hours per response for § 99.201(a)(4)(i)(A), (a)(4)(ii)(A), and (a)(5), the total burden hours for each of these provisions is reduced due to the smaller number of annual responses.

Additionally, the final rule accounts for the estimated annual reporting and recordkeeping burdens for several provisions (§§ 99.201(a)(1), 99.201(a)(2), 99.203(a), 99.501(a)(1), 99.501(b)(1), 99.501(b)(3), 99.501(b)(5), and 99.501(c)). These provisions were omitted from the Paperwork Reduction Act discussion in the preamble to the proposed rule. The final rule also accounts for the statutory reporting burden associated with § 99.201(a)(4).

The agency has submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to send comments regarding information collection by January 19, 1999, to the Dockets Management Branch (address above).

VI. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 99

Administrative practice and procedure, Biologics, Devices, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Acting Commissioner of Food and Drugs, 21 CFR chapter I is amended to read as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 is revised to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 99.401(c) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) Regulatory provisions:

* * * * *

§ 99.401(c), relating to a due diligence determination concerning the conduct of studies necessary for a supplemental application for a new use of a drug or device.

* * * * *

3. Part 99 is added to read as follows:

PART 99—DISSEMINATION OF INFORMATION ON UNAPPROVED/ NEW USES FOR MARKETED DRUGS, BIOLOGICS, AND DEVICES

Subpart A—General Information

Sec.

Subpart B—Information to be Disseminated

Subpart C—Manufacturer's Submissions, Requests, and Applications

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360c, 360e, 360aa–360aaa–6, 371, and 374; 42 U.S.C. 262.

Subpart A—General Information

§ 99.1 Scope.

(a) This part applies to the dissemination of information on human drugs, including biologics, and devices where the information to be disseminated:

(1) Concerns the safety, effectiveness, or benefit of a use that is not included in the approved labeling for a drug or device approved by the Food and Drug Administration for marketing or in the statement of intended use for a device cleared by the Food and Drug Administration for marketing; and

(2) Will be disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency.

(b) This part does not apply to a manufacturer's dissemination of information that responds to a health care practitioner's unsolicited request.

§ 99.3 Definitions.

(a) *Agency* or *FDA* means the Food and Drug Administration.

(b) For purposes of this part, a *clinical investigation* is an investigation in humans that tests a specific clinical hypothesis.

(c) *Group health plan* means an employee welfare benefit plan (as defined in section 3(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(1))) to the extent that the plan provides medical care (as defined in paragraphs (c)(1) through (c)(3) of this section and including items and services paid for as medical care) to employees or their dependents (as defined under the terms of the plan) directly or through insurance, reimbursement, or otherwise. For purposes of this part, the term *medical care* means:

(1) Amounts paid for the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body;

(2) Amounts paid for transportation primarily for and essential to medical care referred to in paragraph (c)(1) of this section; and

(3) Amounts paid for insurance covering medical care referred to in paragraphs (c)(1) and (c)(2) of this section.

(d) *Health care practitioner* means a physician or other individual who is a health care provider and licensed under State law to prescribe drugs or devices.

(e) *Health insurance issuer* means an insurance company, insurance service, or insurance organization (including a health maintenance organization, as defined in paragraph (e)(2) of this section) which is licensed to engage in the business of insurance in a State and which is subject to State law which regulates insurance (within the meaning of section 514(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)(2))).

(1) Such term does not include a group health plan.

(2) For purposes of this part, the term *health maintenance organization* means:

(i) A Federally qualified health maintenance organization (as defined in section 1301(a) of the Public Health Service Act (42 U.S.C. 300e(a)));

(ii) An organization recognized under State law as a health maintenance organization; or

(iii) A similar organization regulated under State law for solvency in the same manner and to the same extent as such a health maintenance organization.

(f) *Manufacturer* means a person who manufactures a drug or device or who is licensed by such person to distribute or market the drug or device. For purposes of this part, the term may also include the sponsor of the approved, licensed, or cleared drug or device.

(g) *New use* means a use that is not included in the approved labeling of an approved drug or device, or a use that is not included in the statement of intended use for a cleared device.

(h) *Pharmacy benefit manager* means a person or entity that has, as its principal focus, the implementation of one or more device and/or prescription drug benefit programs.

(i) A *reference publication* is a publication that:

(1) Has not been written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer;

(2) Has not been edited or significantly influenced by such a manufacturer;

(3) Is not solely distributed through such a manufacturer, but is generally available in bookstores or other distribution channels where medical textbooks are sold;

(4) Does not focus on any particular drug or device of a manufacturer that disseminates information under this part and does not have a primary focus on new uses of drugs or devices that are marketed or are under investigation by a manufacturer supporting the dissemination of information; and

(5) Does not present materials that are false or misleading.

(j) *Scientific or medical journal* means a scientific or medical publication:

(1) That is published by an organization that has an editorial board, that uses experts who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles, and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

(2) Whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

(3) That is generally recognized to be of national scope and reputation;

(4) That is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

(5) That is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers.

(k) *Supplemental application* means:

(1) For drugs, a supplement to support a new use to an approved new drug application;

(2) For biologics, a supplement to an approved license application;

(3) For devices that are the subject of a cleared 510(k) submission and devices that are exempt from the 510(k) process, a new 510(k) submission to support a new use or, for devices that are the subject of an approved premarket approval application, a supplement to support a new use to an approved premarket approval application.

Subpart B—Information to be Disseminated

§ 99.101 Information that may be disseminated.

(a) A manufacturer may disseminate written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling for an approved drug or device or in the statement of intended use for a cleared device, provided that the manufacturer complies with all other relevant requirements under this part. Such information shall:

(1) Be about a drug or device that has been approved, licensed, or cleared for marketing by FDA;

(2) Be in the form of:

(i) An unabridged reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal. In addition, the article must be about a clinical investigation with respect to the drug or device and must be considered to be scientifically sound by the experts described in this paragraph; or

(ii) An unabridged reference publication that includes information about a clinical investigation with respect to the drug or device, which experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of the clinical investigation would consider to be scientifically sound;

(3) Not pose a significant risk to the public health;

(4) Not be false or misleading. FDA may consider information disseminated under this part to be false or misleading if, among other things, the information includes only favorable publications when unfavorable publications exist or excludes articles, reference publications, or other information required under § 99.103(a)(4) or the information presents conclusions that clearly cannot be supported by the results of the study; and

(5) Not be derived from clinical research conducted by another manufacturer unless the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination.

(b) For purposes of this part:

(1) FDA will find that all journal articles and reference publications (as those terms are defined in § 99.3) are scientifically sound except:

(i) Letters to the editor;

(ii) Abstracts of a publication;

(iii) Those regarding Phase 1 trials in healthy people;

(iv) Flagged reference publications that contain little or no substantive discussion of the relevant clinical investigation; and

(v) Those regarding observations in four or fewer people that do not reflect any systematic attempt to collect data, unless the manufacturer demonstrates to FDA that such reports could help guide a physician in his/her medical practice.

(2) A reprint or copy of an article or reference publication is ''unabridged'' only if it retains the same appearance, form, format, content, or configuration as the original article or publication. Such reprint, copy of an article, or reference publication shall not be disseminated with any information that is promotional in nature. A manufacturer may cite a particular discussion about a new use in a reference publication in the explanatory or other information attached to or otherwise accompanying the reference publication under § 99.103.

§ 99.103 Mandatory statements and information.

(a) Any information disseminated under this part shall include:

(1) A prominently displayed statement disclosing:

(i) For a drug, ''This information concerns a use that has not been approved by the Food and Drug Administration.'' For devices, the statement shall read, ''This information concerns a use that has not been approved or cleared by the Food and Drug Administration.'' If the information to be disseminated includes both an approved and unapproved use or uses or a cleared and uncleared use or uses, the manufacturer shall modify the statement to identify the unapproved or uncleared new use or uses. The manufacturer shall permanently affix the statement to the front of each reprint or copy of an article from a scientific or medical journal and to the front of each reference publication disseminated under this part;

(ii) If applicable, the information is being disseminated at the expense of the manufacturer;

(iii) If applicable, the names of any authors of the information who were employees of, or consultants to, or received compensation from the manufacturer, or who had a significant financial interest in the manufacturer during the time that the study that is the subject of the dissemination was conducted up through 1 year after the time the article/reference publication was written and published;

(iv) If applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated; and

(v) The identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

(2) The official labeling for the drug or device;

(3) A bibliography of other articles (that concern reports of clinical investigations both supporting and not supporting the new use) from a scientific reference publication or scientific or medical journal that have been previously published about the new use of the drug or device covered by the information that is being disseminated, unless the disseminated information already includes such a bibliography; and

(4) Any additional information required by FDA under § 99.301(a)(2). Such information shall be attached to the front of the disseminated information or, if attached to the back of the disseminated information, its presence shall be made known to the reader by a sticker or notation on the front of the disseminated information and may consist of:

(i) Objective and scientifically sound information pertaining to the safety or effectiveness of the new use of the drug or device and which FDA determines is necessary to provide objectivity and balance. This may include information that the manufacturer has submitted to FDA or, where appropriate, a summary of such information and any other information that can be made publicly available; and

(ii) An objective statement prepared by FDA, based on data or other scientifically sound information, bearing on the safety or effectiveness of the new use of the drug or device.

(b) Except as provided in paragraphs (a)(1)(i) and (a)(4) of this section, the statements, bibliography, and other information required by this section shall be attached to such disseminated information.

(c) For purposes of this section, factors to be considered in determining whether a statement is ''prominently displayed'' may include, but are not limited to, type size, font, layout, contrast, graphic design, headlines, spacing, and any other technique to achieve emphasis or notice. The required statements shall be outlined, boxed, highlighted, or otherwise graphically designed and presented in a manner that achieves emphasis or notice and is distinct from the other information being disseminated.

§ 99.105 Recipients of information.

A manufacturer disseminating information on a new use under this part may only disseminate that information to a health care practitioner, a pharmacy benefit manager, a health insurance issuer, a group health plan, or a Federal or State Government agency.

Subpart C—Manufacturer's Submissions, Requests, and Applications

§ 99.201 Manufacturer's submission to the agency.

(a) Sixty days before disseminating any written information concerning the safety, effectiveness, or benefit of a new use for a drug or device, a manufacturer shall submit to the agency:

(1) An identical copy of the information to be disseminated, including any information (e.g., the bibliography) and statements required under § 99.103;

(2) Any other clinical trial information which the manufacturer has relating to the effectiveness of the new use, any other clinical trial information that the manufacturer has relating to the safety of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information. For purposes of this part, clinical trial information includes, but is not limited to, published papers and abstracts, even if not intended for dissemination, and unpublished manuscripts, abstracts, and data analyses from completed or ongoing investigations. The reports of clinical experience required under this paragraph shall include case studies, retrospective reviews, epidemiological studies, adverse event reports, and any other material concerning adverse effects or risks reported for or associated with the new use. If the manufacturer has no knowledge of clinical trial information relating to the safety or effectiveness of the new use or reports of clinical experience pertaining to the safety of the new use, the manufacturer shall provide a statement to that effect;

(3) An explanation of the manufacturer's method of selecting the articles for the bibliography (e.g., the databases or sources and criteria (i.e., subject headings/keywords) used to generate the bibliography and the time period covered by the bibliography); and

(4) If the manufacturer has not submitted a supplemental application for the new use, one of the following:

(i) If the manufacturer has completed studies needed for the submission of a supplemental application for the new use:

(A) A copy of the protocol for each completed study or, if such protocol was submitted to an investigational new drug application or an investigational device exemption, the number(s) for the investigational new drug application or investigational device exemption covering the new use, the date of submission of the protocol(s), the protocol number(s), and the date of any amendments to the protocol(s); and

(B) A certification stating that, ''On behalf of [insert manufacturer's name], I certify that [insert manufacturer's name] has completed the studies needed for the submission of a supplemental application for [insert new use] and will submit a supplemental application for such new use to the Food and Drug Administration no later than [insert date no later than 6 months from date that dissemination of information under this part can begin]''; or

(ii) If the manufacturer has planned studies that will be needed for the submission of a supplemental application for the new use:

(A) The proposed protocols and schedule for conducting the studies needed for the submission of a supplemental application for the new use. The protocols shall comply with all applicable requirements in parts 312 of this chapter (investigational new drug applications) and 812 of this chapter (investigational device exemptions). The schedule shall include the projected dates on which the manufacturer expects the principal study events to occur (e.g., initiation and completion of patient enrollment, completion of data collection, completion of data analysis, and submission of the supplemental application); and

(B) A certification stating that, ''On behalf of [insert manufacturer's name], I certify that [insert manufacturer's name] will exercise due diligence to complete the clinical studies necessary to submit a supplemental application for [insert new use] and will submit a supplemental application for such new use to the Food and Drug Administration no later than [insert date no later than 36 months from date that dissemination of information under this part can begin or no later than such time period as FDA may specify pursuant to an extension granted under § 99.303(a)];'' or

(iii) An application for exemption from the requirement of a supplemental application; or

(5) If the manufacturer has submitted a supplemental application for the new use, a cross-reference to that supplemental application.

(b) The manufacturer's attorney, agent, or other authorized official shall sign the submission and certification statement or application for exemption. If the manufacturer does not have a place of business in the United States, the submission and certification statement or application for exemption shall contain the signature, name, and address of the manufacturer's attorney, agent, or other authorized official who resides or maintains a place of business in the United States.

(c) The manufacturer shall send three copies of the submission and certification statement or application for exemption to FDA. The outside of the shipping container shall be marked as ''Submission for the Dissemination of Information on an Unapproved/New Use.'' The manufacturer shall send the submission and certification statement or application for exemption to the appropriate FDA component listed in paragraphs (c)(1) through (c)(3) of this section.

(1) For biological products and devices regulated by the Center for Biologics Evaluation and Research, the Advertising and Promotional Labeling Staff (HFM–602), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852;

(2) For human drug products, the Division of Drug Marketing, Advertising, and Communications (HFD–40), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or

(3) For medical devices, the Promotion and Advertising Policy Staff (HFZ–302), Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850.

(d) The 60-day period shall begin when FDA receives a manufacturer's submission, including, where applicable, a certification statement or an application for an exemption.

§ 99.203 Request to extend the time for completing planned studies.

(a) A manufacturer may request, prior to or at the time of making a submission to FDA under § 99.201, that FDA extend the 36-month time period for completing the studies and submitting a supplemental application for the new use that is the subject of the information to be disseminated. Such request must set forth the reasons that such studies cannot be completed and submitted in a supplemental application within 36 months.

(b) A manufacturer who has certified that it will complete the studies necessary to submit a supplemental application for a new use within a

specified period of time from the date that dissemination of information under this part can begin under § 99.201(a)(4)(ii), but later finds that it will be unable to complete such studies and submit a supplemental application within that time period may request an extension of time from FDA. The manufacturer, in its request for extension, shall identify the product, the new use, and shall:

(1) Describe the study or studies that cannot be completed on time and explain why the study or studies cannot be completed on time;

(2) Describe the current status of the incomplete study or studies and summarize the work conducted, including the dates on which principal events concerning the study or studies occurred; and

(3) Estimate the additional time needed to complete the studies and submit a supplemental application. The requested extension shall not exceed an additional 24 months.

(c) The manufacturer shall send three copies of the request for extension to the same FDA office that received the manufacturer's initial submission and certification statement. The outside of the envelope shall be marked as ''Request for Time Extension—Dissemination of Information on an Unapproved Use.''

§ 99.205 Application for exemption from the requirement to file a supplemental application.

(a) In certain circumstances, described in paragraph (b) of this section, a manufacturer may submit an application for an exemption from the requirement to submit a supplemental application for a new use for purposes of disseminating information on that use.

(b) The manufacturer's application for an exemption shall identify the basis for the proposed exemption and shall include materials demonstrating that it would be economically prohibitive or that it would be unethical to conduct the studies necessary to submit a supplemental application for the new use.

(1) If the basis for the manufacturer's application for exemption is that it would be economically prohibitive to incur the costs necessary to submit a supplemental application for a new use, the manufacturer shall, at a minimum, provide:

(i) Evidence explaining why existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated, are not adequate to support the submission of a supplemental application for the new use. Such evidence shall include an analysis of all data relevant to the safety and effectiveness of the use, a summary of those data, and any documentation resulting from prior discussions with the agency concerning the adequacy of the existing data; and

(ii) Evidence demonstrating that the cost of the study or studies for the new use reasonably exceeds the expected revenue from the new use minus the costs of goods sold and marketing and administrative expenses attributable to the new use of the product. Such evidence shall include:

(A) A description of the additional studies that the manufacturer believes are necessary to support the submission of a supplemental application for the new use, including documentation from prior discussions, if any, with the agency concerning the studies that would be needed, and an estimate of the projected costs for such studies;

(B) The expected patient population for the new use;

(C) The expected revenue for the new use, including an explanation of the price at which the drug or device will be sold;

(D) Any exclusivity for the drug or device for the new use; and

(E) Any other information that the manufacturer has showing that conducting the studies on the new use would be economically prohibitive; and

(iii) An attestation by a responsible individual of the manufacturer or an individual acting on the manufacturer's behalf verifying that the estimates included with the submission are accurate and were prepared in accordance with generally accepted accounting procedures. The data underlying and supporting the estimates shall be made available to FDA upon request. Alternatively, a manufacturer may submit a report of an independent certified public accountant in accordance with the Statement of Standards for Attestation established by the American Institute of Certified Public Accountants and agreed upon procedures performed with respect to the estimates submitted under this section.

(2) If the basis for the manufacturer's application for exemption is that it would be unethical to conduct the studies necessary for the supplemental application for a new use, the manufacturer shall provide evidence:

(i) Explaining why existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated, are not adequate to support the submission of a supplemental application for the new use. Such evidence shall include an analysis of all data relevant to the safety and effectiveness of the new use, a summary of those data, and any documentation resulting from prior discussions with the agency concerning the adequacy of the existing data; and

(ii) Explaining why it would be unethical to conduct the further studies that would be necessary for the approval of the new use. Such evidence shall establish that, notwithstanding the insufficiency of available data to support the submission of a supplemental application for the new use, the data are persuasive to the extent that withholding the drug or device in a controlled study (e.g., by providing no therapy, a placebo, an alternative therapy, or an alternative dose) would pose an unreasonable risk of harm to human subjects. In assessing the appropriateness of conducting studies to support the new use, the manufacturer may provide evidence showing that the new use is broadly accepted as current standard medical treatment or therapy. The manufacturer shall also address the possibility of conducting studies in different populations or of modified design (e.g., adding the new therapy to existing treatments or using an alternative dose if monotherapy studies could not be conducted).

Subpart D—FDA Action on Submissions, Requests, and Applications

§ 99.301 Agency action on a submission.

(a) *Submissions.* Within 60 days after receiving a submission under this part, FDA may:

(1) Determine that the manufacturer does not comply with the requirements under this part and that, as a result, the manufacturer shall not disseminate any information under this part;

(2) After providing the manufacturer notice and an opportunity for a meeting, determine that the information submitted regarding a new use fails to provide data, analyses, or other written matter that is objective and balanced and:

(i) Require the manufacturer to disseminate additional information, including information that the manufacturer has submitted to FDA or, where appropriate, a summary of such information or any other information that can be made publicly available, which, in the agency's opinion:

(A) Is objective and scientifically sound;

(B) Pertains to the safety or effectiveness of the new use; and

(C) Is necessary to provide objectivity and balance; and

(ii) Require the manufacturer to disseminate an objective statement prepared by FDA that is based on data or other scientifically sound information available to the agency and bears on the safety or effectiveness of the drug or device for the new use; and

(3) Require the manufacturer to maintain records that will identify individual recipients of the information that is to be disseminated when such individual records are warranted due to special safety considerations associated with the new use.

(b) *Protocols/Studies.* Within 60 days after receiving a submission under this part, FDA shall:

(1) If the manufacturer has planned studies that will be needed for the submission of a supplemental application for the new use, review the manufacturer's proposed protocols and schedule for completing such studies and determine whether the proposed protocols are adequate and whether the proposed schedule for completing the studies is reasonable. FDA shall notify the manufacturer of its determination; or

(2) If the manufacturer has completed studies that the manufacturer believes would be an adequate basis for the submission of a supplemental application for the new use, conduct a review of the protocols submitted for such studies to determine whether they are adequate. FDA shall notify the manufacturer of its determination.

§ 99.303 Extension of time for completing planned studies.

(a) Upon review of a drug or device manufacturer's proposed protocols and schedules for conducting studies needed for the submission of a supplemental application for a new use, FDA may, with or without a request for an extension from the manufacturer, determine that such studies cannot be completed and submitted within 36 months. The agency may exercise its discretion in extending the time period for completing the studies and submitting a supplemental application. Extensions under this paragraph are not subject to any time limit, but shall be made before the manufacturer begins the studies needed for the submission of a supplemental application for the new use.

(b) The manufacturer may, after beginning the studies needed for the submission of a supplemental application for a new use, request in writing that FDA extend the time period for conducting studies needed for the submission of a supplemental application for a new use and submitting a supplemental application to FDA. FDA may grant or deny the request or, after consulting the manufacturer, grant an extension different from that requested by the manufacturer. FDA may grant a manufacturer's request for an extension if FDA determines that the manufacturer has acted with due diligence to conduct the studies needed for the submission of a supplemental application for a new use and to submit such a supplemental application to FDA in a timely manner and that, despite such actions, the manufacturer needs additional time to complete the studies and submit the supplemental application. Extensions under this paragraph shall not exceed 24 months.

(c) If FDA extends the time period for completing the studies and submitting a supplemental application under paragraph (a) of this section after the manufacturer has submitted a certification under § 99.201(a)(4)(ii)(B), or if FDA grants a manufacturer's request for an extension under paragraph (b) of this section, the manufacturer shall submit a new certification under § 99.201(a)(4)(ii)(B) that sets forth the timeframe within which clinical studies will be completed and a supplemental application will be submitted to FDA.

§ 99.305 Exemption from the requirement to file a supplemental application.

(a) Within 60 days after receipt of an application for an exemption from the requirement of a supplemental application, FDA shall approve or deny the application.

(1) If FDA does not act on the application for an exemption within the 60-day period, the application for an exemption shall be deemed to be approved.

(2) If an application for an exemption is deemed to be approved, FDA may, at any time, terminate such approval if it determines that the requirements for granting an exemption have not been met. FDA shall notify the manufacturer if the approval is terminated.

(b) In reviewing an application for an exemption, FDA shall consider the materials submitted by the manufacturer and may consider any other appropriate information, including, but not limited to, any pending or previously approved applications for exemption submitted by the manufacturer.

(c) FDA may grant an application for an exemption if FDA determines that:

(1) It would be economically prohibitive for the manufacturer to incur the costs necessary to submit a supplemental application for a new use, which at a minimum requires:

(i) That existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated are not adequate to support the submission of a supplemental application for the new use; and

(ii) That the cost of the study or studies for the new use reasonably exceeds the expected revenue from the new use minus the cost of goods sold and marketing and administrative expenses attributable to the new use of the product, and there are not less expensive ways to obtain the needed information; or

(2) It would be unethical to conduct clinical studies needed to support the submission of a supplemental application for the new use because:

(i) Existing data characterizing the safety and effectiveness of the drug or device, including data from the study described in the information to be disseminated are not adequate to support the submission of a supplemental application for the new use; and

(ii) Although available evidence would not support the submission of a supplemental application for the new use, the data are persuasive to the extent that withholding the drug or device in a controlled study would pose an unreasonable risk of harm to human subjects and no studies in different populations or of modified design can be utilized. In determining whether it would be unethical to conduct clinical studies, the agency shall consider, in addition to the persuasiveness of available evidence of effectiveness, whether the new use of the drug or device is broadly accepted as current standard medical treatment or therapy.

Subpart E—Corrective Actions and Cessation of Dissemination

§ 99.401 Corrective actions and cessation of dissemination of information.

(a) *FDA actions based on post dissemination data.* If FDA receives data after a manufacturer has begun disseminating information on a new use and, based on that data, determines that the new use that is the subject of information disseminated under this part may not be effective or may present a significant risk to public health, FDA shall consult the manufacturer and, after such consultation, take appropriate action to protect the public health. Such action may include ordering the manufacturer to cease disseminating

information on the new use and to take appropriate corrective action.

(b) *FDA actions based on information disseminated by a manufacturer.* If FDA determines that a manufacturer is disseminating information that does not comply with the requirements under this part, FDA may:

(1) Provide to the manufacturer an opportunity to bring itself into compliance with the requirements under this part if the manufacturer's noncompliance constitutes a minor violation of these requirements; or

(2) Order the manufacturer to cease dissemination of information and to take corrective action. FDA shall issue such an order only after it has:

(i) Provided notice to the manufacturer regarding FDA's intent to issue an order to cease dissemination; and

(ii) Provided to the manufacturer an opportunity for a meeting. FDA need not provide an opportunity for a meeting if the manufacturer certified that it will submit a supplemental application for the new use within 6 months of the date that dissemination can begin and the noncompliance involves a failure to submit such supplemental application.

(c) *FDA actions based on a manufacturer's supplemental application.* FDA may order a manufacturer to cease disseminating information under this part and to take corrective action if:

(1) In the case of a manufacturer that has submitted a supplemental application for the new use, FDA determines that the supplemental application does not contain adequate information for approval of the new use;

(2) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 6 months, the manufacturer has not, within the 6-month period, submitted a supplemental application for the new use;

(3) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 36 months or within such time as FDA has determined to be appropriate under § 99.303(a) or (b), such manufacturer has not submitted the supplemental application within the certified time, or FDA, after an informal hearing, has determined that the manufacturer is not acting with due diligence to initiate or complete the studies necessary to support a supplemental application for the new use; or

(4) In the case of a manufacturer that has certified that it will submit a supplemental application for the new use within 36 months or within such time as FDA has determined to be appropriate under § 99.303(a) or (b), the manufacturer has discontinued or terminated the clinical studies that would be necessary to support a supplemental application for a new use.

(d) *Effective date of orders to cease dissemination.* An order to cease dissemination of information shall be effective upon date of receipt by the manufacturer, unless otherwise stated in such order.

(e) *Cessation of dissemination by a noncomplying manufacturer.* A manufacturer that begins to disseminate information in compliance with this part, but subsequently fails to comply with this part, shall immediately cease disseminating information under this part. A manufacturer that discontinues, terminates, or fails to conduct with due diligence clinical studies that it certified it would complete under § 99.201(a)(4)(ii) shall be deemed not in compliance with this part. A manufacturer shall notify FDA immediately if it ceases dissemination under this paragraph.

§ 99.403 Termination of approvals of applications for exemption.

(a) FDA may, at any time, terminate the approval of an application for an exemption from the requirement to file a supplemental application if:

(1) The application for an exemption had been deemed to be approved because the agency had not acted on the application within 60 days after its receipt by FDA;

(2) The manufacturer is disseminating written information on the new use; and

(3) FDA determines that it would be economically and ethically possible for the manufacturer to conduct the clinical studies needed to submit a supplemental application for the new use.

(b) If FDA terminates a deemed approval of an application for an exemption under paragraph (a) of this section, FDA also may:

(1) Order the manufacturer to cease disseminating information; and

(2) Order the manufacturer to take action to correct the information that has been disseminated if FDA determines that the new use described in the disseminated information would pose a significant risk to public health.

(c) FDA shall notify the manufacturer if it terminates the deemed approval of an application for an exemption under paragraph (a) of this section. If FDA also issues an order to cease dissemination of information, the manufacturer shall comply with the order no later than 60 days after its receipt.

(d) FDA may, at any time, terminate the approval of an application for an exemption from the requirement to file a supplemental application for a new use if, after consulting with the manufacturer that was granted such exemption, FDA determines that the manufacturer no longer meets the requirements for an exemption on the basis that it is economically prohibitive or unethical to conduct the studies needed to submit a supplemental application for the new use.

(e) If FDA terminates an approval of an application for an exemption under paragraph (d) of this section, the manufacturer must, within 60 days of being notified by FDA that its exemption approval has been terminated, file a supplemental application for the new use that is the subject of the information being disseminated under the exemption, certify, under § 99.201(a)(4)(i) or (a)(4)(ii) that it will file a supplemental application for the new use, or cease disseminating the information on the new use. FDA may require a manufacturer that ceases dissemination of information on the new use to undertake corrective action.

§ 99.405 Applicability of labeling, adulteration, and misbranding authority.

The dissemination of information relating to a new use for a drug or device may constitute labeling, evidence of a new intended use, adulteration, or misbranding of the drug or device if such dissemination fails to comply with section 551 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360aaa) and the requirements of this part. A manufacturer's failure to exercise due diligence in submitting the clinical studies that are necessary for the approval of a new use that is the subject of information disseminated under this part or in beginning or completing such clinical studies shall be deemed a failure to comply with section 551 of the act and the requirements of this part.

Subpart F—Recordkeeping and Reports

§ 99.501 Recordkeeping and reports.

(a) A manufacturer disseminating information under this part shall:

(1) Maintain records sufficient to allow the manufacturer to take corrective action as required by FDA. The manufacturer shall make such records available to FDA, upon request, for inspection and copying. Such records shall either:

(i) Identify, by name, those persons receiving the disseminated information; or

(ii) Identify, by category, the recipients of the disseminated information, unless FDA requires the manufacturer to retain records identifying individual recipients of the disseminated information. Manufacturers whose records identify recipients by category only shall:

(A) Identify subcategories of recipients where appropriate (e.g., oncologists, pediatricians, obstetricians, etc.); and

(B) Ensure that any corrective action to be taken will be sufficiently conspicuous to individuals within that category of recipients;

(2) Maintain an identical copy of the information disseminated under this part; and

(3) Upon the submission of a supplemental application to FDA, notify the appropriate office identified in § 99.201(c) of this part.

(b) A manufacturer disseminating information on a new use for a drug or device shall, on a semiannual basis, submit to the FDA office identified in § 99.201(c) of this part:

(1) A list containing the titles of articles and reference publications relating to the new use of drugs or devices that the manufacturer disseminated to a health care practitioner, pharmacy benefit manager, health insurance issuer, group health plan, or Federal or State Government agency. The list shall cover articles and reference publications disseminated in the 6-month period preceding the date on which the manufacturer provides the list to FDA;

(2) A list identifying the categories of health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, or Federal or State Government agencies that received the articles and reference publications in the 6-month period described in paragraph (b)(1) of this section. The list shall also identify which category of recipients received a particular article or reference publication;

(3) A notice and summary of any additional clinical research or other data relating to the safety or effectiveness of the new use, and, if the manufacturer possesses such clinical research or other data, a copy of the research or data. Such other data may include, but is not limited to, new articles published in scientific or medical journals, reference publications, and summaries of adverse effects that are or may be associated with the new use;

(4) If the manufacturer is conducting studies necessary for the submission of a supplemental application, the manufacturer shall submit periodic progress reports on these studies to FDA. Such reports shall describe the studies' current status (i.e., progress on patient enrollment, any significant problems that could affect the manufacturer's ability to complete the studies, and expected completion dates). If the manufacturer discontinues or terminates a study before completing it, the manufacturer shall, as part of the next periodic progress report, state the reasons for such discontinuation or termination; and

(5) If the manufacturer was granted an exemption from the requirements to submit a supplemental application for the new use, any new or additional information that relates to whether the manufacturer continues to meet the requirements for such exemption. This information may include, but is not limited to, new or additional information regarding revenues from the product that is the subject of the dissemination and new or additional information regarding the persuasiveness of the data on the new use, including information regarding whether the new use is broadly accepted as current standard medical treatment or therapy.

(c) A manufacturer shall maintain a copy of all information, lists, records, and reports required or disseminated under this part for 3 years after it has ceased dissemination of such information and make such documents available to FDA for inspection and copying.

Dated: November 17, 1998.

Michael A. Friedman,

Acting Commissioner for Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

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Low-level waste shipment manifest information; transfer for disposal and manifests; technical amendment; published 9-21-98

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Temporary assistance for needy families program—
State child poverty rate determination methodology; comments due by 11-23-98; published 9-23-98

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Note: The list of Public Laws for the second session of the 105th Congress has been completed and will resume when bills are enacted into law during the first session of the 106th Congress, which convenes on January 6, 1999.

A cumulative list of Public Laws for the second session of the 105th Congress will be published in the **Federal Register** on November 30, 1998.

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